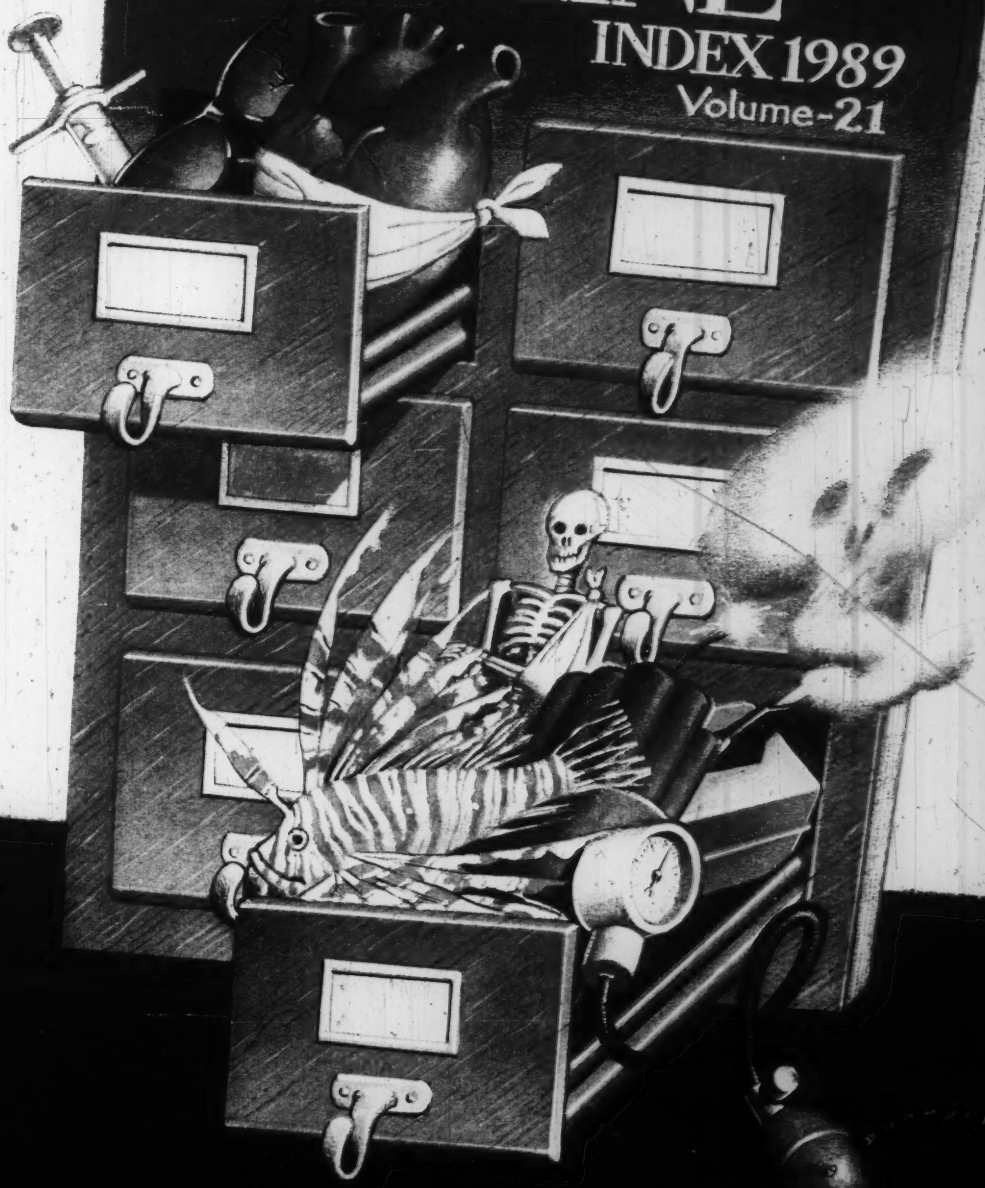
EMERGENCY MEDICINE

INDEX 1989

Volume-21



INDEX 1989

Key to issues and dates in Volume 21
*In entries, **boldface** numbers refer to issue and lightface to pages in that issue.*

Issue No.	Date				
1	JANUARY 15	8	APRIL 30	15	SEPTEMBER 15
2	JANUARY 30	9	MAY 15	16	SEPTEMBER 30
3	FEBRUARY 15	10	MAY 30	19	OCTOBER 15
4	FEBRUARY 28	11	JUNE 15	18	OCTOBER 30
5	MARCH 15	12	JUNE 30	19	NOVEMBER 15
6	MARCH 30	13	JULY 15	20	NOVEMBER 30
7	APRIL 15	14	AUGUST 15	21	DECEMBER 15

A

Abdomen
Acute
Congenital hypertrophic pyloric stenosis as cause of, **10**:42
Diabetic ketoacidosis as cause of, **20**:20
In the elderly, **3**:23
Perforated duodenal ulcer as cause of, **14**:143
PID as cause of, **8**:33
Hard, in infant, as sign of child abuse, **16**:110
Mass in, as sign of ileocolic intussusception, **8**:129
Pain in
Aortic aneurysm as cause of, **3**:97
Atheromatous embolism as cause of, **21**:73
Heavy metal poisoning as cause of, **8**:86
Irritable bowel syndrome as cause of, **16**:67
Measles as cause of, **17**:97
Nonspecific, diagnosis and treatment of, **6**:63
Urinary retention as cause of, misdiagnosis of, **13**:118
Palpation of, tricks for, **2**:103; **4**:82; **16**:86
Trauma to
Penetrating, pleural effusion after, **11**:93
Ultrasonography vs peritoneal lavage for, **15**:45
Vascular, avoidance of MAST suit in, **20**:88

Abortion
As cause of vaginal bleeding, **9**:87
Septic, listeriosis as cause of, **15**:32

Abscess
Orbital or subperiosteal, as complication to sinusitis, **18**:28, **21**:97
Peritonsillar, as complication of pharyngitis, **18**:32
Subdiaphragmatic, pleural effusion as sign of, **11**:96
Tubo-ovarian, associated with PID, **8**:33, 38
Unexplained fever caused by, **5**:112

Abuse
See *Children; Drugs; Women*

Accessory tragi
Diagnosis and removal of, **14**:108

Acetaminophen
For febrile seizures in children, **11**:197
Overdose of, liver damage from, **15**:82

Acetazolamide
For glaucoma, **1**:115; **9**:68
For high-altitude illness
Prophylaxis, **5**:38
Treatment, **5**:31
For retinal artery occlusion, **20**:60

Acetonitrile
As source of cyanide poisoning, **9**:45

Acetylcysteine
Contraindications to, in acute asthma, **7**:93

Acid-base disorders
Mixed, normal anion gap in, **11**:9 (letter)

Acidosis
Metabolic, in diabetic ketoacidosis, **20**:20
Wide-gap metabolic, identifying diabetic cause of, **8**:22
See also *Ketoacidosis*

Acquired Immune Deficiency Syndrome
See *AIDS*

Acromioclavicular separation
Diagnosis and treatment of, **5**:66

Acromion
Injury to, x-ray diagnosis of, **3**:183

Acropustulosis
Of infancy, diagnosis of, **17**:90

Actinomycosis
Neck mass, caused by, **4**:66

Acyclovir
For herpes in AIDS, **2**:38

Addiction
See *Alcoholism; Drugs*

Adenocarcinoma
Epistaxis as sign of, **3**:97
Ethmoidal sinus, neck mass caused by, **4**:62

Adenoma
Sebaceum, as sign of tuberous sclerosis, in a child, **7**:73
With ulcerative colitis, **19**:56

Adenopathy
Hilar, as sign of measles, **17**:99
Mediastinal, as cause of superior vena cava syndrome, **15**:69

Aerodontalgia
Diving ascent as cause of, **10**:63

Aerogastralgia
Scuba diving as cause of, **10**:64

AIDS
Infections in
CMV, **2**:36; **16**:37
Fungal, **15**:18, 23
Listeriosis, **15**:32
Opportunistic, **2**:25
Pneumocystis pneumonia, **2**:26; **9**:71
Syphilis, rapid progression of, **3**:105
Toxoplasmosis, **17**:36
Tuberculosis, in the homeless, **2**:35; **4**:24
Extrapulmonary, **14**:101
Interstitial lung disease as manifestation of, **19**:64
Medicolegal issues in disclosure of, **6**:126
Thrombocytopenia as sign of, **8**:158
See also *HIV*

Air
Free, in diagnosis of perforated duodenal ulcer, **14**:144
See also *Pneumothorax; Embolism*

Airway
Inhalation injury to, **7**:54
Obstruction of, **7**:63; **13**:35; **19**:83

Akathisia
Diagnosis of, **19**:33

Akinesia
Diagnosis and treatment of, **19**:23

Albumin
Salt-poor, for ascites, **18**:45

Albuterol
Nebulized, for acute asthma, **7**:93

Alcohol
Importance of avoiding, in influenza, **17**:75
Withdrawal, as cause of adult-onset seizures, **1**:23

Alcoholism
In battered women, incidence of, **11**:107
Diabetic crises associated with, **20**:23
Hepatitis caused by, methylprednisolone for, **20**:90
In the homeless, **4**:36
Liver enzyme elevations in, **6**:70
Mistaken for diabetic ketoacidosis, **8**:22
Niacin contraindicated in, **20**:53

Perforated duodenal ulcer in, **14**:150
As predisposition to anaerobic pneumonia, **1**:34
Risk of, in persons with essential tremor, **19**:30
Septic bursitis in, **8**:71
Suicide in, **4**:75

Alkalosis
Hyperchloremic, in pyloric stenosis, **10**:45

Allergy
To hair dye, contact dermatitis caused by, **10**:98
Role in chronic bronchitis, **20**:70
Testing for, in pediatric asthma, **11**:123
See also *Anaphylaxis;* specific allergens

Alopecia
As sign of thallium poisoning, **1**:40

Altitude
High, contraindications to, **5**:35
Illness due to
  Diagnosis and treatment of, **5**:20
  Prevention of, **5**:35

Alveolitis
As sign of interstitial lung disease, **19**:63
In toxic gas inhalation, **7**:59

Amantadine
For influenza, **17**:64
  With acute bronchitis, **8**:113

Amiloride
For ascites, **18**:42

Aminocaproic acid
For prevention of rebleeding in hyphema, **9**:58

Aminoglycosides
Avoidance of, in ascites, **18**:48
Minimizing toxicity from, **2**:92

Aminotransferase
Asymptomatic elevation of, **6**:69

Amitriptyline
For irritable bowel syndrome, **16**:72

Ammonia
Inhalation injury from, **7**:60

Amphotericin B
For fungal infection in the immunocompromised, **15**:20, 23

Amputation
Traumatic, initial management of, **14**:140

Amyl nitrate
For auscultatory diagnosis of heart murmurs, **10**:26

Anaphylaxis
Diagnosis and treatment of, **16**:51
Differentiated from toxic shock syndrome, **8**:122

Anemia
Assessment and treatment of, **14**:179
  In chronic disorders, **14**:181
Heavy metal poisoning as cause of, **8**:88
From iron deficiency, in adolescent athletes, **17**:51
Pernicious, **14**:191
  B_{12} deficiency as sign of, **11**:102; **14**:79
Sickle cell, effect of high altitude on, **5**:36

Anesthesia
For hand or wrist injury, **3**:94; **13**:107
Local
  Of children, trick for, **14**:195; **21**:111
  Diphenhydramine for lidocaine allergy in, **8**:68
  Trick for painless injection of, **8**:68
Nitrous oxide used for, **3**:117
Regional, procedure for Bier block, **12**:73; **19**:11 (letter)
As risk factor for DVT, **4**:88

Aneurysm
Abdominal aortic, diagnosis of, **3**:97
Cerebral
  Headache as warning sign before rupture, **13**:105
  Hemorrhagic stroke caused by, **14**:120
  Medicolegal implications of ED misdiagnosis of, **16**:40

Angina
Ludwig's, neck mass caused by, **4**:65
Musculoskeletal, diagnosis of, **19**:45
Prinzmetal's, hyperventilation-induced MI in, **11**:77
Silent myocardial ischemia associated with, **20**:97
Unstable
  Diagnosis and treatment of, **3**:39
  Differentiated from acute MI, **15**:59
  Emergent hypertension in, **8**:95
  Heparin as MI prophylaxis in, **11**:74
  Noninvasive assessment of, **10**:59
In young adults, diagnosis of, **2**:60

Angioedema
Hereditary, differentiated from anaphylaxis, **16**:56
As sign of anaphylaxis, **16**:51

Angiography
For atheromatous embolism, **21**:73
Coronary
  For myocarditis, **1**:89
  For silent ischemia, **20**:100
  For unstable angina, **3**:39
    Alternatives to, **10**:59
Fluorescein, in diabetic retinopathy, **11**:90
Pulmonary, for suspected embolism, **4**:90; **7**:48
For suspected stroke, **14**:119
See also *Arteriography; Venography*

Ankle
Splinting of, trick for, **10**:31
Sports injuries to, **13**:18
Trauma
  Assessment and treatment of, **1**:62
  Pitfalls in diagnosing, **6**:114

Antibiotics
Anaphylaxis caused by, **16**:52
For ascites, **18**:48
For bronchitis
  Acute, limitations of, **8**:116
  Chronic, **20**:71
Combinations of, for PID, **8**:37, 38
For complicated pharyngitis, **18**:32
For duodenal ulcer, perforated, **14**:49
Empiric
  For COPD exacerbation, **7**:96
  For suspected infection in the elderly, **18**:91
For endocarditis, **3**:49
  Prophylaxis during dental procedures, **1**:82
  On the right side, **11**:72
Failure of, in otitis media, **18**:16
For fever in cancer, **21**:56
For gonorrhea, resistant, **11**:81
For hand injuries, **14**:142
For infection with chronic bronchitis, **20**:75
For listeriosis, **15**:44
For mouth wounds, prophylaxis, **10**:83; **19**:89
For pelvic inflammatory disease, **6**:31
For pneumonia, **7**:40, 83
  In Pneumocystis, toxic effects of, **9**:74
For pyelonephritis, **10**:83
As risk factor for fungal infection in the immunocompromised, **15**:20
For septic bursitis, **8**:72
For sinusitis, **21**:93
See also specific agents

Anticholinergics
For acute asthma, **7**:26
For irritable bowel syndrome, **16**:72
See also specific agents

Anticoagulants
For atrial fibrillation, **11**:180
For calf DVT, **6**:59
For cerebral thombosis, **2**:109
Guidelines for prescribing, **11**:173
Interactions with other drugs, in the elderly, **4**:55
For ischemic stroke, **14**:120
For pulmonary embolism, **7**:48; **13**:151
A risk factor for atheromatous embolism, **21**:73
For thrombophilia, **6**:52
See also specific agents

Anticonvulsants
For adult-onset seizures, **1**:27
For cocaine-induced seizures, **21**:35
Prophylactic, after pediatric febrile seizure, **11**:198
For theophylline overdose, **15**:87
See also specific agents

Antidepressants
In interstitial cystitis, **11**:155

Antifungals
Topical, for candidiasis, **20**:120

Antihistamines
For anaphylaxis, **16**:58

continued

INDEX 1989

Antivirals
For HPV infection in men, **13**:125
For influenza, **17**:64
See also specific agents

Anxiety
Performance, treatment of, in musicians, **11**:129
As risk factor in anaphylaxis, **16**:55

Aortic dissection
Acute, misdiagnosed as hyperventilation, **14**:129
Chest pain in young adults caused by, **2**:66
Emergent hypertension caused by, **8**:96

Aphthous stomatitis
Recurrent, diagnosis and treatment of, **9**:35

Appendicitis
Acute, ruling out, in suspected PID, **8**:33
Atypical presentations of, **9**:39
In children, **12**:45
In the elderly, diagnosis and treatment of, **3**:23
Nonspecific abdominal pain caused by, **6**:67
Pelvic pain in women caused by, **6**:32
Unexplained fever caused by, **5**:119

Arcing
In high-voltage electrical injury, **13**:93

ARDS
As complication in pneumonia, **7**:85
Diagnosis and management of, **7**:67

Arm
Abnormality of child's, rickets as cause of, **7**:73
Pseudoaneurysm in
After blunt trauma, **13**:147
Iatrogenic, **21**:69
Rash, from photosensitization contact dermatitis, **14**:108
Trauma, pitfalls in diagnosing, **5**:63

Arrhythmias
Dizziness caused by, **18**:74
Lyme disease as cause of, **3**:64
In pericarditis, **8**:135
As possible cause of syncope, **14**:40
With stroke, management of, **14**:115
Ventricular, differentiated from supraventricular, **9**:42
See also specific arrhythmias

Arsenic
Poisoning, diagnosis and treatment of, **8**:88

Arsine
Poisoning, diagnosis and treatment of, **8**:88

Arteriography
After high-voltage electrical injury, **13**:94
Atheromatous embolism caused by, **21**:73
For pseudoaneurysm, **13**:147
For suspected stroke, **14**:118, 120
See also *Angiography*

Arteriosclerosis
Of vessels of ocular fundus, diagnosis of, **17**:29
See also *Atherosclerosis*

Arteritis
Temporal, sudden vision loss caused by **9**:69; **20**:65

Arthritis
Ankle injury as cause of, **1**:72
Bacterial, as cause of acute joint pain, **16**:82
Bursitis differentiated from, **8**:71
Juvenile rheumatoid, differentiated from Lyme disease, **3**:65
Lyme disease as cause of, **3**:65
Musculoskeletal angina caused by, **19**:48
Septic, diagnosis of, in child's painful elbow, **6**:103
Sudden onset of, diagnosis of, **16**:80

Arthropathy
Of temporomandibular joint, **19**:74

Arthroscopy
For repair of knee injury, **3**:133

Asbestosis
Diagnosis and treatment of, **19**:64

Ascites
Management of, new approaches to, **18**:42

Aspartate aminotransferase
In diagnosis of MI, **14**:159

Aspergillus
Infection in the immunocompromised, **15**:18

Asphyxiation
In grain storage units, **3**:169

Aspiration
Bursal fluid, in bursitis, **8**:71
Catheter, in pneumothorax, **2**:45
Pulmonary
Anaerobic pneumonia caused by, **1**:34
Associated with ARDS, **7**:68
Sinus, for diagnosis of sinusitis, **21**:89

Aspirin
Epistaxis from use of, in cancer patient, **8**:129
As MI prophylaxis, **11**:74
Reye's syndrome in children taking, **17**:64
Sensitivity to, differentiated from anaphylaxis, **16**:56

Asterixis
Related to myoclonus, **19**:32

Asthma
Acute, pharmacologic management of, **7**:23
Anaphylaxis with, **16**:51
Beta agonists for, **7**:24
Bronchitis related to, **8**:110, 112
Chronic, **20**:71
In children
Diagnosis and treatment of, **11**:119
Preventive measures for, **11**:124
Respiratory failure in, **7**:90

Asystole
From electrical injury, **13**:93
From Lyme carditis, **14**:54

Ataxia
In mountain sickness, **5**:24

Atelectasis
Chest tube as cause of, **20**:131
Lobar, bronchoscopy for, **7**:88
Round lesions on chest x-ray caused by, **2**:54

Atherosclerosis
Silent ischemia associated with, **20**:100
In young adults, **2**:65
See also *arteriosclerosis*

Athletes
Adolescent, iron deficiency in, **17**:51
See also specific injuries and sites

Athlete's foot
See *Tinea pedis*

Atrial septal defect
In the elderly, auscultatory diagnosis of, **10**:25

Atropine sulfate
For organophosphate poisoning, **3**:157

Audiometry
In ear or facial trauma, **18**:20
In otitis media, **18**:19

Auscultation
For diagnosis of pericarditis, **8**:134
For heart murmurs in the elderly, **10**:21
For placement of endotracheal tube, **17**:93
In pulmonary function testing, **13**:44

Automobile accidents
Cervical trauma in, from seat belt restraint, **17**:46
Incidence of spinal cord injury in, **9**:22
See also specific injuries and sites

Autopsy
Of child, requesting parents' permission for, **6**:82

Avulsion
Of greater tuberosity of humerus, **5**:67
Injury to hand, **3**:81
Traumatic enucleation of eye, management of, **9**:56

AZT
See *Zidovudine*

B

Back pain
Imaging techniques in diagnosis of, **11**:164
Need for x-rays to rule out cancer, **18**:63

Baclofen
For limb spasticity, **19**:22

Bacteremia
As complication in septic bursitis, **8**:72
Staphylococcal
Endocarditis after, **3**:49
Endocarditis prophylaxis in, **8**:42

Balance
Assessment of, in gait disorders of the elderly, **8**:53

Bandemia
As sign of infection in afebrile elderly patients, **18**:91

Barium swallow
For diagnosis of dysphagia, **1**:51
For esophageal foreign body, **21**:45
For hypertrophic pylorus in infants, **10**:44

Barotitis media
Cause and treatment of, **10**:62

Barotrauma
Of ascent, diagnosis and treatment of, **10**:64
Dental, tooth decay as cause of, **10**:63
Of descent, diagnosis and treatment of, **10**:62

Batteries
Button, management of ingestion of, **17**:42; **21**:51

Beck's triad
As sign of cardiac tamponade in pericarditis, **8**:135

Bees
See *Hymenoptera stings*

Bends
Joint, from scuba diving, **10**:70
Skin, from scuba diving, **10**:71

Benzodiazepines
For performance anxiety in musicians, **11**:129

Beta blockers
For cocaine intoxication, **21**:34
For emergent hypertension, **8**:96
For performance anxiety in musicians, **11**:129
Topical, for acute glaucoma, **9**:68
For unstable angina, **3**:40

Bicarbonate
For diabetic ketoacidosis, risks vs benefits of, **8**:31

Bier block
For regional anesthesia, procedure for, **12**:73; **19**:11 (letter)

Bile acids
Oral, for symptomatic gallstones, **11**:131

Bile duct
Stones in, nonsurgical management of, **11**:84

Biliary tract
Injury, from blunt trauma, diagnosis and treatment of, **5**:95

Biopsy
Bone, in insufficiency fracture, **9**:77
Colon, showing dysplasia, **19**:55
Of dysplastic nevi, to rule out melanoma, **16**:106
For HPV infection in men, **13**:122
For interstitial lung disease, **19**:70
Liver, for hepatitis, **16**:136
Of neck mass, **4**:68
Right ventricular endomyocardial, for myocarditis, **1**:89

Bismuth subsalicylate
For traveler's diarrhea, **12**:85; **18**:9 (letter)

Bites
Brown recluse spider, **14**:39
Insect, ear inflammation caused by, **4**:71
Tick
As clue to Lyme carditis, **14**:56
Ehrlichiosis caused by, **14**:102
Likelihood of Lyme disease after, **10**:49
Q fever caused by, **14**:174
See also *Envenomations; Stings*

Bladder
Pain, interstitial cystitis as cause of, **11**:149

Bleeding
Anemia caused by, **14**:179
Control of, in hand injuries, **14**:132
Disorders, diagnosis and management of, **8**:145
Ear, as sign of epistaxis from aspirin therapy, **8**:129
After electrical cord injury to child, **13**:90
Esophageal variceal, endoscopic ligation for, **6**:37
Gastrointestinal
Dexamethasone as cause of, **8**:48
Upper
Epistaxis caused by, **17**:35
Management of, **18**:77
In hyphoma, prevention of, **9**:58
Peritoneal or retroperitoneal, after vertical trauma, **14**:211
Scalp, rapid control of, **6**:99
Time, abnormal, **8**:158
Vaginal
Diagnosis and treatment of, **9**:85
As sign of cervical cancer in the elderly, **16**:26
As sign of endometrial cancer in the elderly, **16**:27
See also *Epistaxis; Hemorrhage; Menstruation*

Blepharitis
Diagnosis and treatment of, **1**:103

Blood
Counts, to diagnose infection without fever in the elderly, **18**:91
Drawing, trick for, **20**:57
Loss, assessment of, **18**:77
Occult, in stool, in detecting colon cancer, **16**:91
Transfusion
Anaphylaxis caused by, **16**:52
As cause of fever in cancer, **21**:56
Malaria transmission by, **13**:34
As source of hepatitis, **16**:124, 135
For upper GI bleeding, **18**:78, 83

Blood patch
Epidural, vs caffeine, for post-lumbar puncture headache, **13**:126

Bone
Cancer
Differentiated from pelvic insufficiency fracture, **9**:77; **21**:173
Metastatic, misdiagnosed as bursitis, **15**:27
Chicken, swallowed, x-ray diagnosis of, **15**:97
Hamate, fracture of, diagnosis of, **3**:88
Marrow
Analysis of, in anemia, **14**:184
Effect of nitrous oxide on, **3**:118
Trauma
From a fall, **14**:209
In hand injuries, **14**:133
See also specific bones

Boric acid
Ingestion of, triage and treatment for, **1**:85

Botulism
Diagnosis and treatment of, **2**:94
Toxin, for focal dystonias, **11**:129
Weakness caused by, **4**:103, 109

Bowel
Inflammatory disease of, risk for cancer with, **19**:52
Injury, splenic rupture associated with, **5**:100
Irritable, diagnosis and treatment in acute phase of, **16**:67

Brain stem
Herniation of, from nitrous oxide abuse, **3**:124

Breast
Cancer, metastatic, misdiagnosed as bursitis, **15**:27

Breathing
Interpreting patterns of, **13**:44
Mouth, as indication for rectal temperature measurement, **20**:114

Bronchitis
Acute, diagnosis and treatment of, **8**:109; **20**:68
Chronic
Acute exacerbations of, **20**:75
Associated with COPD, **8**:112
Diagnosis and treatment of, **20**:70
Respiratory failure in, **7**:94

Bronchodilators
For acute bronchitis, **8**:113
For COPD exacerbation, **7**:94

continued

Bronchoscopy
For inhalation injury, **7**:59
For lung infections, **7**:40
For pneumonia-associated atelectasis, **7**:88

Bronchospasm
In coelenterate envenomation, **12**:30
See also *Asthma*

Bruce protocol
In assessment of unstable angina, **10**:59

Burns
Differentiating thermal from electrical, **13**:86
Of eye, assessment and management of, **9**:54
Of hand
Chemical, **3**:80
Splint to prevent flexion deformities in, **12**:66
Minor, trick for soothing, **16**:86
Surface, from electrical injury, **13**:93

Bursitis
Differentiating septic from aseptic, **8**:71
Inferior calcaneal, as cause of heel spur, **13**:22
Musculoskeletal angina caused by, **19**:48
Resemblance to metastatic cancer, **15**:27
Retrocalcaneal, **13**:22

Butoconazole
For candidiasis, **20**:128

C

Caffeine
For post-lumbar puncture headache, **13**:126

Calcification
Mitral annular
In the elderly, auscultatory diagnosis of, **10**:23
X-ray diagnosis of, **11**:203

Calcium channel blockers
For atheromatous embolism, **21**:76
In emergent hypertension, **8**:96
For unstable angina, **3**:40
See also specific agents

Campylobacter
Traveler's diarrhea caused by, **12**:80

Cancer
Back pain caused by, **11**:164
X-rays to rule out, **18**:63
Bone, insufficiency fracture as mimic of, **21**:173
Cervical
Associated with HPV, **13**:121
In the elderly, **16**:24
Treatment of, **16**:26
And endometrial, vaginal dischage in, **20**:120
Colon
Early detection of, with sigmoidoscopy, **16**:91
Misdiagnosed as peptic ulcer, **5**:45
Risk of, with inflammatory bowel disease, **19**:52
Endometrial
In the elderly, **16**:27
Vaginal bleeding in, **9**:87
Fever of unknown origin in, causes of, **21**:55
Gastric outlet obstruction caused by, **10**:45
Gynecologic, in the elderly, **16**:24
Liver, risk of, with hepatitis, **16**:131
Lung, differentiated from round pneumonia, **2**:54
Metastatic, misdiagnosed as bursitis, **15**:27
Neck mass caused by, **4**:61
Ovarian, in the elderly, **16**:28
Prostate, metastatic, bleeding from aspirin therapy for, **8**:129
Skin, diagnosis of, **17**:90
Superior vena cava syndrome caused by, **15**:69
Thyroid, misdiagnosed as goiter, **2**:91
Vulvar, in the elderly, **16**:28
See also specific cancers

Candida
Endophthalmitis from, differentiated from CMV retinitis, **16**:39
Infection
Of finger web space, diagnosis of, **11**:167
In the immunocompromised, **15**:18
Vaginal, diagnosis and treatment of, **20**:118

Captopril
For emergent hypertension, **8**:99

Carbon monoxide
Inhalation injury from, **7**:54
Poisoning
In acute mountain sickness, **5**:23
On the farm, **3**:169
Hyperbaric oxygen for, **7**:54; **12**:46
O_2 saturation in, **7**:54; **12**:9 (letter)

Carcinoma
See *Cancer*

Cardiac tamponade
As complication of pericarditis, **8**:131
From penetrating chest trauma, **20**:82

Cardiomyopathy
Hypertrophic obstructive, in the elderly, auscultatory diagnosis of, **10**:23
Influenza-related, **17**:75

Carditis
Lyme, diagnosis and treatment of, **14**:54

Caries
Nursing, in small child, **18**:68

Cartilage
Cricoid, resemblance to foreign body on x-ray, **15**:98

Cataract
Formation of, after high-voltage electrical injury, **13**:94
Endophthalmitis as postsurgical complication of, **9**:68

Catecholamine
Release, hypertensive emergency caused by, **8**:96

Catfish
Envenomation by, **12**:38

Catheter
For aspiration of pneumothorax, **2**:45
Foley
Indwelling, trick for removing maggots from, **18**:41
For tamponade of vaginal bleeding, **9**:92
After high-voltage electrical injury, **13**:93
Indwelling, as cause of DVT, **4**:88
For removal of foreign body
From child's nose, **16**:86
From esophagus, **17**:44; **21**:52
Procedure for inserting, **2**:85
As risk factor for fungal infection in the immunocompromised, **15**:23
Subclavian, misplaced, x-ray diagnosis of, **2**:119; **12**:101
Swan-Ganz
Endocarditis caused by, **8**:42
Misplaced, x-ray diagnosis of, **8**:175
Tracheal, for ongoing oxygen therapy in chronic bronchitis, **20**:72
See also *Intubation*

Cauterization
To control scalp bleeding, **13**:75

Cefotaxime
For ascites, **18**:45

Ceftriaxone
For penicillin-resistant gonorrhea, **11**:81

Cellulitis
Of the foot, with DVT, **18**:94
Orbital
As complication of sinusitis, **18**:28; **21**:88, 97
Diagnosis and treatment of, **1**:103; **9**:68

Cephalization
Of pulmonary blood flow, seen on chest x-ray, **17**:124

Cephalosporins
Selection of, for perforated duodenal ulcer, **14**:149
See also specific agents

Cervix
Cancer of, in the elderly, **16**:24
Purulent discharge from, as sign of PID, **8**:33

Chalazion
Diagnosis and treatment of, **1**:103

Charcoal
Activated, vs ipecac, for toxic ingestion, **14**:154

Cheilosis
Angular, diagnosis of, **8**:105

continued

Chemotherapy
As cause of fever in cancer, **21**:55
For ovarian cancer in the elderly, **16**:36
As risk factor for fungal infection, **15**:18

Chest
Pain
Acute aortic dissection as cause of, **14**:129
Hyperventilation-induced MI as cause of, **11**:77
Musculoskeletal, diagnosis of, **19**:45
Myocarditis as cause of, **1**:89
Noncardiac, trick for diagnosing, **6**:16 (letter); **12**:9 (letter)
Pericarditis as cause of, **8**:131
Unstable angina or acute MI as cause of, **15**:60
In young adult
Diagnosis of, **2**:60
Misdiagnosis of, **12**:99
Stab wounds to, management of, **21**:171
Trauma, penetrating, pitfalls in managing, **20**:82
Tube
Lung atelectasis caused by, **20**:131
Misplaced, x-ray evaluation of, **10**:113

Chicken pox
See *Varicella*

Children
Abuse of
Recognizing in ED, **16**:110
Signs and treatment of, **11**:113
Adolescent
Athletic, iron deficiency in, **17**:51
Suicide risk factors in, **4**:77
With unrecognized diabetic ketoacidosis, **20**:81
Varicella in, diagnosis of, **15**:49
Anesthetization of, topical, trick for, **21**:111
Appendicitis in, with peritonitis, **12**:45
Artificial-nail remover poisoning in, **9**:45
Asthma in
Diagnosis and treatment of, **11**:119
Prophylaxis for, **11**:124
Theophylline for, **7**:26
Bacterial meningitis in, dexamethasone for, **8**:45
Of battered women, risk of abuse for, **11**:113
Blunt trauma in, causes of, **5**:95
Calcaneal apophysis in, x-ray appearance of, **5**:125
Cervical spine injury in, **9**:30
Normal variant, mimicking, **1**:117
Coelenterate envenomation in, **12**:30
Conjunctivitis in, diagnosis and treatment of, **1**:102
Coughing in, trick for telephone diagnosis of, **14**:195
Croup in, trick for humidifying air to treat, **16**:86
Death of, informing parents of, procedures for, **6**:74; **12**:9 (letter)
Ear examination in, trick for, **8**:68
Elbow injury in, x-ray diagnosis of, **5**:80
Electrical cord injuries in, **13**:90
Epinephrine overdose in, **21**:167
Esophageal foreign bodies in, **21**:46, 51
Febrile seizures in, diagnosis and treatment of, **11**:186
Fractures in
Clavicle, greenstick, **5**:66
Rib, occult, **16**:110
Tibia, stress, **14**:213
Ileocolic intussusception in, **8**:129
Influenza in, **17**:62
Immunization for, **17**:84
Insect bite on ear of, **4**:71
Insecticide poisoning in, **3**:154
Intubation of, **19**:81
Ketoacidosis in undiagnosed diabetes in, **20**:20
Liquid medication for, trick for administering, **21**:111
Lye ingestion by, **4**:71
Measles in, diagnosis and treatment of, **17**:97
Immunization for, new recommendations for, **17**:103
Nail deformity in, **15**:49
Nasal foreign body in, trick for removing, **16**:86
Neck masses in, **4**:62
Nevus sebaceus of Jadassohn on scalp of, **5**:59
Oral examination of, trick for, **10**:31
Orbital infections with sinusitis in, **21**:97
Osteomyelitis in, diagnosis of, **6**:103
Otoscopy of, tricks for, **6**:96; **20**:57
Oxygenation of, trick for, **2**:103
Perleche in, diagnosis of, **8**:105
Restraint of, for examination, trick for, **14**:195
Rickets in, diagnosis of, **7**:73
Splenic injury in, nonsurgical management of, **5**:100
Steroid inhalation by, trick for maximizing, **14**:195
Suturing, tricks for, **12**:42; **13**:78; **14**:195
Tay-Sachs disease in, ophthalmologic diagnosis of, **6**:103
Thrombophlebitis in, **3**:75
Tooth decay in, nursing caries as cause of, **18**:67
Tuberous sclerosis in, **7**:73
See also *Infants*

Chlamydia
Coinfection with gonorrhea, **16**:94
Routine screening for, in high-risk patients, **16**:93
TWAR-agent
Differentiated from measles, **17**:99
Pneumonia caused by, **14**:171

Chloramphenicol
For ehrlichiosis, **14**:106
With nafcillin, for otitis media, **18**:18

Chlorine
Inhalation injury from, **7**:60

Chloroquine
For malaria
Possible resistance to, **13**:129
Prophylaxis, **13**:141

Chlorpromazine
Chlorpropamide erroneously substituted for, **6**:34; **12**:9 (letter)

Chlorpropamide
Hypoglycemic coma caused by, **6**:34; **10**:80; **12**:9 (letter)

Cholangiography
For biliary tract injuries, **5**:95, 99

Cholangitis
Differentiated from acute cholecystitis, **11**:136
Unexplained fever caused by, **5**:119

Cholecystectomy
Alternatives to, **11**:131
For gallstone-related pancreatitis, **2**:53
Prophylactic, unnecessary in asymptomatic diabetics, **14**:49

Cholecystitis
Acute, gallstones as cause of, **11**:136
Danger of, in diabetics with gallstones, **14**:52
Differentiated from
Acutely irritable bowel, **16**:67
PID, **6**:31
Incidence of, after sphincterotomy, **11**:84

Choledocholithiasis
Nonsurgical management of, **11**:84

Cholesterol
Elevated, niacin for, **20**:50

Cholinesterase
Inhibition of, in pesticide poisoning, **3**:154

Chondrocalcinosis
See *Pseudogout*

Chondromalacia patellae
See *Knee, runner's*

Chorea
Diagnosis and treatment of, **19**:32

Choroid
Disorders of, **17**:30

Chronic obstructive pulmonary disease
See *COPD*

Chymopapain
As cause of anaphylaxis, **16**:55

Ciprofloxacin
For traveler's diarrhea, **12**:86

Circulating immune-complex disease
Acute joint pain caused by, **16**:84

Cirrhosis
With non-A, non-B hepatitis, **16**:135
See also *Liver disease*

Clavicle
Greenstick fracture of, in children, **5**:66
Painful, x-ray diagnosis of, **13**:156

continued

Clotrimazole
For candidiasis, **20**:128
For fungal infection in the immunocompromised, **15**:20

Clubbing
As sign of idiopathic pulmonary fibrosis, **19**:64

Coagulation
Defects
DVT caused by, **6**:47
Vaginal bleeding caused by, **9**:86
Disseminated intravascular, diagnosis and treatment of, **8**:146

Coagulopathy
Preoperative assessment of, **11**:148
Washout, as precipitant of pseudoaneurysm, **21**:72

Cobalamin
Serum levels, in pernicious anemia, **11**:102

Cocaine
Abuse, acute rhabdomyolysis associated with, **6**:100
Cardiovascular effects of, **21**:26
Emergent hypertension caused by, **8**:98

Codeine
For cough in acute bronchitis, **8**:112

Coin swallowing
In college students, management of, **11**:200; **21**:46, 51
X-ray diagnosis of, **21**:51

Colchicine
For gout or pseudogout, **16**:82

Colitis
Infectious, differentiated from irritable bowel syndrome, **16**:70
Ulcerative, risk of cancer from, **19**:52

Colonoscopy
For cancer screening in inflammatory bowel disease, **19**:52
See also *Sigmoidoscopy*

Coma
Hyperosmolar
In elderly diabetics, **8**:32
Movement disorders as precursor to, **21**:37
Nonketotic, warning signs of, **20**:31
Hypoglycemic
Chlorpropamide as cause of, **6**:34; **10**:80; **12**:9 (letter)
In diabetics, **8**:32
Prognostic model for, **10**:37

Compartment syndrome
See *Syndrome*

Compresses
Trick for warming, **13**:78

Compression
Pneumatic, inadvisability of, for traumatic shock, **20**:86
Venous, for DVT prophylaxis, **4**:89

Condoms
Inadequacy of, in preventing HPV transmission, **13**:121

Condylomata
In HPV infection, **13**:121
As sign of secondary syphilis, **3**:107

Confidentiality
Legal restrictions on, **6**:125

Conjunctivitis
Diagnosis and treatment of, **1**:100; **9**:64

Consent
For ED treatment, **2**:8 (letter)
Obtaining, for treatment of minor, **7**:11 (letter)

Constipation
In elderly patients, trick for relieving, **10**:31
With irritable bowel syndrome, **16**:67

Contrast medium
As cause of anaphylaxis, **16**:55

Contusion
Myocardial, cardiac enzymes in diagnosis of, **5**:47
Spinal cord, coagulation necrosis in, **9**:24

COPD
Chronic bronchitis associated with, **8**:112
Differentiated from chronic bronchitis, **20**:77
Influenza immunization in patients with, **17**:85
Rectal temperature measurement in, **20**:113
Respiratory failure in, **7**:94
As risk factor for influenza, **17**:63
Risks of long-term corticosteroid treatment in, **17**:114

Copper
Poisoning, diagnosis and treatment of, **8**:88

Cor pulmonale
Chronic bronchitis as cause of, **20**:72

Cornea
Abrasions of, diagnosis and treatment of, **9**:62
From liquid detergent exposure, **15**:53
Disorders of, as cause of red eye, **1**:103
Foreign body in, trick for removal of, **4**:76
Infection of, extended-wear contact lenses as cause of, **9**:67
Trauma to, from chemical burns, **9**:54

Coronary artery disease
Silent ischemia in, **20**:97

Coronoid process
Fracture, pitfalls in diagnosing, **5**:79

Corpus luteum
Rupture, as cause of pelvic pain, **6**:33

Corticosteroids
See *Steroids*

Counseling
For battered women, **11**:108
For parents, after death of child, **6**:84, 94

Creatine kinase
Serum, serial measurement of, to diagnose MI, **14**:159; **15**:64

Cricothyroidotomy
As alternative to oral intubation in cervical injury, **21**:168
Oxygen delivery in, trick for, **4**:82

Crohn's disease
Risk of cancer with, **19**:52, 58
Unexplained fever caused by, **5**:119

Cromolyn sodium
For acute asthma, **7**:25
For chronic asthma, **7**:93

Croup
Trick for humidifying air to treat, **16**:86

Crush injury
Of hand, treatment of, **3**:82

Cryotherapy
For HPV infection in men, **13**:122

Cryptococcosis
In AIDS, **2**:35
In the immunocompromised, **15**:22

Culdocentesis
For pelvic peritoneal irritation in women, **6**:24

Curettage
Endometrial, in diagnosis of vaginal bleeding, **9**:87

Cyanide poisoning
Artificial-nail removers as source of, **9**:45
Treatment of, **15**:87

Cyst
Branchial cleft, neck mass caused by, **4**:68
Dental lamina, or gingival, in newborn, **18**:68
Foveal, or hole, diagnosis of, **17**:24
Ovarian, ruptured, pelvic pain caused by, **6**:33
Thyroglossal duct, neck mass caused by, **4**:68

Cystic duct
Obstruction of, **11**:136

Cystitis
Interstitial, diagnosis and treatment of, **11**:149

Cytomegalovirus
Infection, in AIDS, **2**:36
Retinitis in the immunocompromised, **16**:37

D

Dacryocystitis
Diagnosis and treatment of, **1**:102; **9**:68

Dapsone
For Pneumocystis pneumonia prophylaxis, **9**:76

Death
Brain, of child, parents' acceptance of, **6**:83
Child's, informing parents of, **6**:74; **12**:9 (letter)
At home, **1**:9 (letter)

Debridement
After high-voltage electrical injury, **13**:93
Of wounds, maggots for, **21**:111

Decompression sickness
Effects and management of, **10**:70
Types of, **10**:66

Decongestants
For sinusitis, **18**:25; **21**:88, 94
Topical, for complicated sinusitis, **18**:29

Defect
Atrial septal, in the elderly, auscultatory diagnosis of, **10**:25
Ventricular septal, in the elderly, auscultatory diagnosis of, **10**:24

Dehydration
In acute mountain sickness, **5**:23, 38
In diabetic ketoacidosis, **8**:20; **20**:22
As sign of perforated duodenal ulcer, **14**:143

Delusions
Indications of, in psychiatric interview, **14**:32

Dementia
Signs of, in psychiatric interview, **14**:32

Dental procedures
Endocarditis prophylaxis before, **1**:82

Dentists
Nitrous oxide abuse among, **3**:121

Depression
Gait impairment as sign of, in the elderly, **8**:52
As risk factor for suicide, **4**:76
Signs of, in psychiatric interview, **14**:28

Dermatitis
In coelenterate envenomation, **12**:28
Contact, hair dye allergy as cause of, **10**:98
Factitial, diagnosis of, **2**:42
Herpetiformis, diagnosis and treatment of, **16**:74
Perioral, diagnosis of, **5**:59
Photosensitization contact, **14**:108

Dermatomyositis
Diagnosis of, **1**:57

Dermatosis papulosa nigra
On face, diagnosis of, **11**:167

Detachment
Posterior vitreous, diagnosis of, **17**:23
Retinal
  Diagnosis of, **17**:30
  Sudden loss of vision caused by, **20**:66

Detergent
Ingestion, home management of, **15**:53

Dexamethasone
For high-altitude cerebral edema, **5**:31
For high-altitude illness prophylaxis, **5**:41
To prevent hearing loss in bacterial meningitis, **8**:45

Dextromethorphan
For cough in acute bronchitis, **8**:112

Diabetes
Adolescent, unrecognized, **20**:81
Asymptomatic gallstones in, nonsurgical approach to, **14**:49
Crises in, diagnosis and management of, **20**:20
Foot problems in, **18**:41
In the homeless, **4**:35
Hypoglycemia in, from chlorpropamide and renal failure, **10**:80
Malignant external otitis associated with, **5**:53
Movement disorders associated with, **21**:37
Pneumonia in, aggressive treatment needed for, **4**:49
Pseudohyponatremia in, **12**:87; **20**:23
Retinopathy in, diagnosis and treatment of, **11**:87
Tuberculosis prophylaxis in, **21**:63
Undiagnosed, ketoacidosis as sign of, **20**:22
See also *Ketoacidosis*

Diagnoses
Bogus or "wastebasket," medicolegal implications of, **18**:51

Diaphragm
Contraceptive, toxic shock syndrome associated with, **8**:120
Injury to
  In penetrating chest trauma, **20**:82
  Splenic rupture associated with, **5**:100

Diarrhea
Fecal impaction as cause of, **5**:45
With irritable bowel syndrome, **16**:67
As sign of anaphylaxis, **16**:52
Traveler's
  Diagnosis and treatment of, **12**:77
  Prophylaxis for, **12**:86; **18**:9 (letter)

Diazepam
For hyperglycemic seizures, **21**:37
For pediatric febrile seizures, **11**:197

Diet
For control of nonketotic hyperglycemic movement disorders, **21**:38
Deficiencies, in the homeless, **4**:28
Restrictions, for irritable bowel syndrome, **16**:70
Role of, in interstitial cystitis, **11**:151
As source of iron to correct deficiency, **17**:55
See also *Food*

Difluoromethylornithine
For Pneumocystis pneumonia, **9**:75

Dilation
Of pupils
  Accidental, diagnosis of, **4**:49
  Before ophthalmoscopy, **17**:20

Diltiazem
For unstable angina, **3**:45

Dimethyl sulfoxide
For interstitial cystitis, **11**:154

Diphenhydramine
For hepatitis, **16**:136
For local anesthesia, **8**:68

Diphenoxylate
For prevention of traveler's diarrhea, **12**:85

Diphtheria
Differentiated from botulism, **2**:94

Diplopia
In orbital fracture, **9**:61

Dipsticks
Urine, reliability of, for detecting infection, **19**:41

Disequilibrium
See *Dizziness*

Disk
Optic, disorders and diagnosis of, **17**:23
Spinal, degeneration of, back pain caused by, **11**:164

Dislocation
Ankle, diagnosis and reduction of, **6**:121
Elbow, diagnosis and reduction of, **5**:79
Finger
  Diagnosis and reduction of, **5**:89
  Taping of, **3**:88
Hip, diagnosis and reduction of, **6**:108
Knee, diagnosis and reduction of, **6**:112
Patellar, diagnosis and reduction of, **6**:111
Shoulder, diagnosis and reduction of, **5**:67, 73
Sternoclavicular, diagnosis and reduction of, **5**:66

continued

Subtalar, of foot, diagnosis and reduction of, **6**:122
Wrist, diagnosis and reduction of **5**:89

Diuretics
For ascites, **18**:42
Interactions with other drugs, in the elderly, **4**:55
See also specific drugs

Diverticulitis
In the elderly, diagnosis and treatment of, **3**:23

Diverticulosis
In the elderly, **3**:24

Diving
Marine animal envenomation during, **12**:26
Prevention of, **12**:41
Medical emergencies in, **10**:61
Prevention of injury during, **10**:79

Dizziness
Diagnosis of, simple approach to, **18**:71
See also *Vertigo*

Doxycycline
For malaria prophylaxis, **13**:144

Drugs
Abuse of
Acute rhabdomyolysis associated with, **6**:100
In battered women, **11**:107
Cardiovascular effects caused by, **21**:26
Emergent hypertension caused by, **8**:98
Endocarditis associated with, **8**:42; **11**:71
In the homeless, **4**:28
Legal implications of certifying end of, **13**:95
Acute reactions to, in the elderly, **4**:50
Adult-onset seizures caused by, **1**:23
Bleeding disorders caused by, **8**:146
Cardiac, as risk factor for pneumonia, **7**:33
Effects of, on thyroid function testing, **13**:61
Fever caused by, in cancer, **21**:56
Generic, potential for confusion of, **12**:9 (letter)
Hyperglycemic crisis precipitated by, **20**:22
Interstitial lung disease caused by, **19**:63
Liver enzyme elevation caused by, **6**:70
Macrocytic anemia caused by, **14**:184, 186
Myoclonus caused by, **19**:32
Overdose of
Activated charcoal vs ipecac for, **14**:154
Emergent hypertension caused by, **8**:98
Resistance to
Enterococcal, **16**:59
In malaria, **13**:129
In tuberculosis, **14**:101
Toxic epidermal necrolysis caused by, **14**:68
Tremor caused by, **19**:29
Unexplained fever caused by, **5**:110
See also specific agents

Duodenum
Perforated ulcer of, diagnosis and treatment of, **14**:143

Dust
As cause of interstitial lung disease, **19**:63

Dysphagia
Coin-swallowing game as cause of, **11**:200
Diagnosis of, **1**:51
As sign of HPV infection, **13**:121

Dysplasia
Colonic, as risk factor for cancer, **19**:55, 61

Dyspnea
Progressive, as sign of interstitial lung disease, **19**:63
As sign of diabetic ketoacidosis, **15**:27
As sign of pneumonia in quadriplegic, **14**:129
As sign of superior vena cava syndrome, **15**:69
Tests to find cause of, **13**:35

Dysrhythmias
Cocaine as cause of, **21**:26

Dystonia
Diagnosis and treatment of, **19**:33
Focal, in musicians, **11**:129

Dysuria
As symptom of appendicitis, **9**:40
As symptom of diverticulitis in the elderly, **3**:25

EF

Ear
Barotraumatic effects on, in scuba diving, **10**:62
Emergencies of, requiring referral, **18**:16
Growths near, diagnosis of, **14**:107
Herpes zoster infection of, diagnosis of, **3**:75
Inner, disorders of, as cause of vertigo, **16**:113
Pain, as sign of malignant external otitis, **5**:54
Swimmer's, differentiated from malignant external otitis, **5**:54
Swollen, insect bite as cause of, **4**:71
Trauma, emergent or complicated, **18**:19, 33
See also specific disorders

Echinodermata
Envenomation by, **12**:32

Echocardiography
For bacteremia, to rule out endocarditis, **3**:49
For effusions in pericarditis, **8**:135
For endocarditis, **11**:72; **12**:61
For myocardial contusion, **5**:47

Eclampsia
Treatment of, as hypertensive emergency, **8**:94

Edema
Cerebral, high-altitude, diagnosis and treatment of, **5**:23, 31
Of extremity, as sign of toxic shock syndrome, **8**:119
Facial, as sign of superior vena cava syndrome, **15**:69
Laryngeal, danger of, with anaphylaxis, **16**:51
Macular, diagnosis of, **17**:24
Pericardial, cardiac tamponade caused by, **8**:135
Pulmonary
From agricultural toxins, **3**:164
In ARDS, **7**:68
Emergent hypertension in, **8**:95
High-altitude, diagnosis and treatment of, **5**:24
Reexpansion, after pneumothorax, **10**:80
As risk factor for bacterial pneumonia, **7**:34

Effusion
Pericardial, from influenza, **17**:76
Pleural, after abdominal trauma, **11**:93

Ehrlichiosis
Diagnosis and treatment of, **14**:102

Elbow
Arthritis in child's, **6**:103
Bursitis in, **8**:71
Dermatitis herpetiformis on, **16**:74
Injury, assessment and treatment of, **5**:74
Miner's, diagnosis and treatment of, **8**:71
Nerve entrapment syndromes of, in musicians, **11**:129

Elderly patients
Abdominal pain in, **6**:67
Acute abdomen in, **3**:23
Acute drug reactions in, **4**:50
Aminotransferase elevations in, associated with heart failure, **6**:69
Bile duct stones in, nonsurgical management of, **11**:84
Bronchitis in
Acute, **8**:110
Chronic, **20**:71
Cholecystectomy for, advisability of, **11**:131
Choosing preoperative tests for, **11**:141
Coagulation disorders in, **8**:152
Constipated, trick for relieving, **10**:31
COPD in, dangers of long-term corticosteroid treatment of, **17**:114
Diabetic, nonketotic hyperosmolar coma in, **8**:32
Drug reactions in, **4**:50
Gait disorders in, treatment for, **8**:51
Gynecologic cancer in, **16**:24
Heart murmurs in, interpretation of, **10**:21
Hip fracture in, **6**:108
Homeless, **4**:21
Infection in, without fever, diagnosis of, **18**:91
Influenza in, **17**:63
Immunization for, **17**:84
Insufficiency fractures of pelvis in, **9**:77
Listeriosis in, **15**:31
Macular degeneration in, **17**:24
Paget's disease in, liver enzyme elevation caused by, **6**:70
Pneumonia in, **7**:77, 82
Without fever, **7**:39
Preop tests in, choice of, **11**:14
Seizures in, causes of, **1**:22
Senile purpura in, diagnosis of, **12**:58
Sigmoidoscopy in, to screen for colon cancer, **16**:91

continued

TIGAN®

(trimethobenzamide HCl)

Indications: Tigan is indicated for the control of nausea and vomiting.

Contraindications: The injectable form of Tigan in children, the suppositories in premature or newborn infants, and use in patients with known hypersensitivity to trimethobenzamide are contraindicated. Since the suppositories contain benzocaine they should not be used in patients known to be sensitive to this or similar local anesthetics.

Warnings:

Caution should be exercised when administering Tigan to children for the treatment of vomiting. Antiemetics are not recommended for treatment of uncomplicated vomiting in children and their use should be limited to prolonged vomiting of known etiology. There are three principal reasons for caution:

1. There has been some suspicion that centrally acting antiemetics may contribute, in combination with viral illnesses (a possible cause of vomiting in children), to development of Reye's syndrome, a potentially fatal acute childhood encephalopathy with visceral fatty degeneration, especially involving the liver. Although there is no confirmation of this suspicion, caution is nevertheless recommended.
2. The extrapyramidal symptoms which can occur secondary to Tigan may be confused with the central nervous system signs of an undiagnosed primary disease responsible for the vomiting, e.g. Reye's syndrome or other encephalopathy.
3. It has been suspected that drugs with hepatotoxic potential, such as Tigan, may unfavorably alter the course of Reye's syndrome. Such drugs should therefore be avoided in children whose signs and symptoms (vomiting) could represent Reye's syndrome. It should also be noted that salicylates and acetaminophen are hepatotoxic at large doses. Although it is not known that at usual doses they would represent a hazard in patients with the underlying hepatic disorder of Reye's syndrome, these drugs, too, should be avoided in children whose signs and symptoms could represent Reye's syndrome, unless alternative methods of controlling fever are not successful.

Tigan may produce drowsiness. Patients should not operate motor vehicles or other dangerous machinery until their individual responses have been determined. Reye's syndrome has been associated with the use of Tigan and other drugs, including antiemetics, although their contribution, if any, to the cause and course of the disease hasn't been established. This syndrome is characterized by an abrupt onset shortly following a nonspecific febrile illness, with persistent, severe vomiting, lethargy, irrational behavior, progressive encephalopathy leading to coma, convulsions and death.

Usage In Pregnancy: Trimethobenzamide hydrochloride was studied in reproduction experiments in rats and rabbits and no teratogenicity was suggested. The only effects observed were an increased percentage of embryonic resorptions or stillborn pups in rats administered 20 mg and 100 mg/kg and increased resorptions in rabbits receiving 100 mg/kg. In each study these adverse effects were attributed to one or two dams. The relevance to humans is not known. Since there is no adequate experience in pregnant or lactating women who have received this drug, safety in pregnancy or in nursing mothers has not been established.

Precautions: During the course of acute febrile illness, encephalitides, gastroenteritis, dehydration and electrolyte imbalance, especially in children and the elderly or debilitated, CNS reactions such as opisthotonos, convulsions, coma and extrapyramidal symptoms have been reported with and without use of Tigan or other antiemetic agents. In such disorders caution should be exercised in administering Tigan, particularly to patients who have recently received other CNS-acting agents (phenothiazines, barbiturates, belladonna derivatives). It is recommended that severe emesis should not be treated with an antiemetic drug alone; where possible the cause of vomiting should be established. Primary emphasis should be directed toward the restoration of body fluids and electrolyte balance, the relief of fever and relief of the causative disease process. Overhydration should be avoided since it may result in cerebral edema.

The antiemetic effects of Tigan may render diagnosis more difficult in such conditions as appendicitis and obscure signs of toxicity due to overdosage of other drugs.

Adverse Reactions: There have been reports of hypersensitivity reactions and Parkinson-like symptoms. There have been instances of hypotension reported following parenteral administration to surgical patients. There have been reports of blood dyscrasias, blurring of vision, coma, convulsions, depression of mood, diarrhea, disorientation, dizziness, drowsiness, headache, jaundice, muscle cramps and opisthotonos. If these occur, the administration of the drug should be discontinued. Allergic-type skin reactions have been observed; therefore, the drug should be discontinued at the first sign of sensitization. While these symptoms will usually disappear spontaneously, symptomatic treatment may be indicated in some cases.

Note: The injectable form is intended for intramuscular administration only; it is not recommended for intravenous use.

How Supplied: CAPSULES* 100 mg, 250 mg, Inactive Ingredients: Lactose, Magnesium Stearate and Starch.

SUPPOSITORIES* 100 mg, 200 mg, contains 2% benzocaine in a base compounded with polysorbate 80, white beeswax and propylene glycol monostearate.

INJECTABLES*† Ampuls: 100 mg/ml (2 ml) 0.2% parabens (methyl and propyl) as preservatives, 1 mg sodium citrate and 0.4 mg citric acid as buffers and pH adjusted to approximately 5.0 with sodium hydroxide.

Thera-Ject® Disposable Syringes: 100 mg/ml (2 ml) contains 200 mg trimethobenzamide hydrochloride compounded with 0.45% phenol as preservative, 1 mg sodium citrate and 0.4 mg citric acid as buffers, 0.2 mg disodium edetate as stabilizer and pH adjusted to approximately 5.0 with sodium hydroxide.

Vials: 100 mg/ml (20 ml) 0.45% phenol as preservative, 0.5 mg sodium citrate and 0.2 mg citric acid as buffers and pH adjusted to approximately 5.0 with sodium hydroxide.

*TIGAN, in all dosage forms, is contraindicated in premature and newborn infants.

†TIGAN injectables are contraindicated in children.

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INDEX 1989

Tuberculosis prophylaxis for, **21**:63
Vision loss in, sudden, diagnosis and treatment of, **9**:69

Electrical injury
High-voltage, management of, **13**:86
Low-voltage, management of, **13**:90

Electrocardiography
For chest pain, **19**:45
To determine effects of influenza, **17**:75
To distinguish acute MI from unstable angina, **15**:61
Exercise, for unstable angina, **10**:59
For high-voltage electrical injury, **13**:94
For Lyme carditis, **14**:56
For pericarditis, **8**:134
Preoperative, indications for, **11**:142
To rule out arrhythmia after syncope, **14**:40
Screening for silent ischemia, **20**:100
For unstable angina, **3**:40
For upper GI bleeding, **18**:84
For ventricular tachycardia, **9**:44

Electrocautery
To control scalp bleeding, **13**:75

Electromyography
For muscular paralysis, **4**:109

Electrophoresis
For identification of isoenzymes, **6**:73

Embolectomy
Surgical, criteria for, **7**:51

Embolism
Air
Risk of, in nitrous oxide use, **3**:124
From scuba diving, **10**:64
Arterial, in decompression sickness, **10**:70
Atheromatous, diagnosis and treatment of, **21**:73
Central retinal artery, as cause of acute vision loss, **9**:69
Cerebral, as cause of stroke, **14**:112
Pulmonary
Diagnosis and treatment of, **7**:47
After inhalation injury, **7**:60
Risks of, from DVT in calf, **6**:59
Silent, with DVT, **13**:151
Treatment of DVT to prevent, **4**:87
Unexplained fever caused by, **5**:114

Emergency Medicine
20th anniversary of magazine, **3**:3; **8**:7 (letter)

Emphysema
Chronic bronchitis associated with, **8**:112; **20**:72
Respiratory failure in, **7**:94
From scuba diving, **10**:64

Empyema
Pulmonary, diagnosis and treatment of, **1**:33

Encephalitis
Influenza-related, treatment of, **17**:70

Encephalopathy
Hepatic
Associated with movement disorders, **21**:37
Corticosteroid therapy for, **20**:92
Hypertensive, diagnosis and treatment of, **8**:94
From nitrous oxide abuse, **3**:121

Endarterectomy
After stroke, **14**:122
Vs medical management, **2**:109

Endocarditis
Antibiotic prophylaxis for, during dental procedures, **1**:82
Echocardiography in diagnosis and prognosis for, **11**:72; **12**:61
Infective, in intravenous drug abusers, **11**:71
Listeria monocytogenes as cause of, **15**:32
Right-sided, short-course therapy for, **8**:42
Risk factors for, in staph bacteremia, **3**:49

Endometrium
Cancer of, in the elderly, **16**:27

Endophthalmitis
Postsurgical, as ocular emergency, **9**:68

Endoscopy
Esophageal
For foreign bodies, **21**:45
For variceal bleeding, **6**:38
For ingested coins, **11**:200
For upper GI bleeding, **18**:84

Enteritis
Unexplained fever caused by, **5**:119

Enterococci
Penicillin-resistant, **16**:59

Envenomations
Hymenoptera, **16**:52
Marine animal, presentation and treatment of, **12**:26

Enzymes
Cardiac
In diagnosis of myocardial contusion, **5**:47
Serial measurement of, to diagnose MI, **14**:159; **15**:64
Hepatic, asymptomatic elevations of, **6**:69

Epilepsy
As consequence of febrile seizures in children, **11**:197
Idiopathic, as cause of adult-onset seizures, **1**:20
Surgery for, risks vs benefits of, **18**:58

Epinephrine
For acute asthma, **7**:93
Administration of, error in, **21**:167
For anaphylaxis, **16**:58
For bleeding scalp, **13**:75
For epistaxis, **5**:120
For shock, contraindications to, **20**:88

Epistaxis
Aspirin-induced, in cancer patient, **8**:129
Assessment and management of, **17**:35
Control of
Procedure for, **5**:120
Trick for applying pressure, **16**:86
Peptic ulcer as source of, **17**:35
Risk factors for, in nasal intubation, **10**:111
As sign of adenocarcinoma, **3**:97
As sign of bleeding disorder, **8**:145
Spontaneous, as cause of hemotympanum, **5**:63

Erythema
Chronicum migrans, as sign of Lyme disease, **3**:58
Multiforme
Diagnosis and treatment of, **19**:36
Differentiated from Lyme disease, **14**:68
Nodosum, as cause of acute joint pain, **16**:85

Erythrocyte sedimentation rate
For determining when to x-ray for lower back pain, **18**:63
High, as sign of temporal arteritis, **20**:65
In malignant external otitis, **5**:55

Erythromycin
For syphilis, **3**:115

Esophagitis
Candidal, in the immunocompromised, **15**:20

Esophagoscopy
For removal of foreign bodies, **17**:44

Esophagus
Button battery lodged in, management of, **17**:42; **21**:51
Foreign body in
Diagnosis and management of, **21**:45
Procedure for removing, **2**:85
Variceal bleeding in, treatment of, **6**:37
See also *Intubation*

Estrogen
As risk factor for endometrial cancer in the elderly, **16**:27
For severe vaginal bleeding, **9**:92

Ethylene glycol
Trick for identifying, with Wood's light, **8**:68

Eustachian tube
Dysfunction of, associated with diving injury, **10**:62

Exercise
Anaphylaxis caused by, **16**:52
Elevated aminotransferase associated with, **6**:70
Importance of avoiding, in influenza, **17**:75
Therapeutic
For ankle injury, **1**:69; **13**:32
For foot injury, **13**:20
For knee injury, **3**:141

Extubation
Proper procedure for, **14**:89

Eye
Abscess, as complication of sinusitis, **21**:88, 97
Anhydrous ammonia damage to, **3**:164
Black, diagnosis and treatment of, **9**:58
Examination
In facial burns, trick for, **8**:68
Fluorescein, trick for, **13**:78
Foreign body in, **1**:108; **9**:55, 61
Occult, **18**:94
Trick for detecting, **2**:103
Trick for removal, **4**:76
Fundus disorders, detection of, **17**:20
Globe rupture, recognition and management of, **9**:55
Laceration, diagnosis of, **9**:55
Liquid detergent injury to, treatment of, **15**:53
Muscle weakness, in myasthenia gravis, **4**:105
Ointment, trick for applying, **16**:86
Pressure, measurement of, to check for injuries with orbital fractures, **13**:83
Putting drops in, trick for, **13**:78
Red, diagnosis and treatment of, **1**:100
Retinitis, **16**:37
Signs
Of serious facial trauma, **18**:30
Of Tay-Sachs disease, **6**:103
Sinusitis affecting, **18**:28
Sudden loss of vision in, **9**:69; **20**:59
Trauma
Assessment and treatment of, **9**:52
Referral for, importance of, **17**:30
Unilateral dilation of, diagnosis of, **4**:49

Eyelid
Disorders, as cause of redness, **1**:103
Laceration, assessment and treatment of, **9**:62

Face
Dermatosis papulosa nigra on, diagnosis of, **11**:168
Pain, as sign of sinusitis, **21**:87, 90
Squeeze, in scuba diving, **10**:64
Trauma, **18**:20

Fasciculation
Diagnosis and treatment of, **19**:31

Fasciitis
Plantar, **13**:22

Fecal impaction
Incontinence and diarrhea caused by, **5**:45
Trick for relieving, **10**:31

Femur
Fractured, assessment and treatment of, **6**:110

Fever
Absence of, with infection in the elderly, **7**:39; **18**:91
Cat-scratch, neck mass caused by, **4**:65
As guideline for pyelography in pyelonephritis, **5**:123
Paroxysms of, as sign of malaria, **13**:132
Q, diagnosis and treatment of, **14**:174
Rectal temperature measurement to detect, **20**:113
Rheumatic,
Acute, **5**:119
As cause of acute joint pain, **16**:85
Rocky Mountain spotted, differentiated from
Ehrlichiosis, **14**:102
Toxic shock syndrome, **8**:123
Scarlet, differentiated from toxic shock syndrome, **8**:122
Seizures in children caused by, **11**:186
As sign of
Child abuse, in infant, **16**:110
Fungal infection in the immunocompromised, **15**:23
Influenza, **17**:62
Undiagnosed diabetes, **20**:81
Unexplained,
Associated with cancer, **21**:55
Diagnosis of, **5**:108

Fibrillation
Atrial, efficacy of anticoagulants for, **11**:180
Peripheral, as sign of neuropathy, **19**:31
Ventricular, from high-voltage electrical injury, **13**:86, 93
See also *Arrhythmias*

Fibrosis
Detrusor, as cause of reduced bladder capacity, **11**:151
Pulmonary
In ARDS, **7**:68
Idiopathic, diagnosis and treatment of, **19**:63

Fibula
Fractured, assessment of, **6**:11

Filter
For pulmonary embolism prophylaxis, **4**:93; **7**:51

Finger
Baseball, diagnosis and treatment of, **5**:92
Candida infection of web of, chronic, **11**:167
Dislocated
Assessment and reduction of, **5**:89
Taping of, **3**:88
Injured
Crush, trick for cleaning, **18**:41
Rotational deformity of, **5**:90
Ischemic, work-related, **17**:119
Mallet, splinting of, **3**:88
Sutured, trick for avoiding hematoma in, **4**:82
Swollen, tricks for removing ring from, **20**:57
See also *Thumb*

Fingernail
Artificial, removers of, as source of cyanide poisoning, **9**:45
Deformed, diagnosis of, **15**:49
Dermatomyositis surrounding, **1**:57

Fire coral
Envenomation by, **12**:28

continued

Fishhook
Removal of, trick for, **12**:42

Fistula
Perilymph, in barotrauma of inner ear, **10**:63

Flow-volume loops
For assessing acute asthma, **7**:23
In inhalation injury, **7**:60
Interpretation of, **13**:35, 42

Flowers
Garden, toxicity from, signs and treatment of, **11**:50

Fluconazole
For fungal infection in the immunocompromised, **15**:26

Flucytosine
For fungal infection in the immunocompromised, **15**:20, 23

Fluorescein
For corneal abrasions, **1**:107
For diagnosing diabetic retinopathy, **11**:89
Examination of eye, trick for, **13**:78

Flushing
As sign of anaphylaxis, **16**:51

Food
Anaphylaxis caused by, **16**:52
Drug interactions with, in the elderly, **4**:56
Role of, in irritable bowel syndrome, **16**:70
As source of listeriosis, **15**:31
As source of toxoplasmosis, **17**:36
Undercooked, traveler's diarrhea caused by, **12**:80
See also *Diet*

Foot
Deformity, gait impairment caused by, in the elderly, **8**:53
Diabetic, cleaning maggots from, **18**:41
Fractures, assessment and treatment of, **6**:122
Infection
  Fungal, diagnosis of, **10**:97
  Likelihood of, after nail puncture wound, **21**:81
Orthopedic anatomy of, **6**:121
Pain, as sign of atheromatous embolism, **21**:74
Puncture wounds, assessment and treatment of, **6**:57
Swollen, unsuspected DVT as cause of, **18**:94
Trauma
  Pitfalls in diagnosing, **6**:122
  Sports, **13**:18
  X-ray evaluation of, **7**:99

Foreign body
Airway compromise from, in infant, **16**:86
Esophageal
  Button battery as, management, **21**:51
  Coin as, **11**:200; **21**:51
  Diagnosis and management of, **21**:45
  Procedure for removing, **2**:85
In eye
  Diagnosis and treatment of, **1**:108; **9**:55, 61
  Importance of searching for, after injury, **18**:94
  Trick for detecting, **2**:103
In foot puncture wounds, examining for, **6**:59
In hand injuries, **14**:134
Nasal, trick for removing, **16**:86
Posterior lamina of cricoid cartilage mistaken for, **15**:98
Under the skin, trick for finding with needle, **13**:78
Vaginal, as cause of bleeding, **9**:86
See also *Ingestion*

Foscarnet
For CMV retinitis, **16**:39

Fovea
Cyst on or hole in, diagnosis of, **17**:24

Fracture
Blow-out, assessment and treatment of, **9**:58
Clavicle, greenstick, **5**:66
Facial, assessment and management of, **18**:29
From a fall, **14**:209
Foot, from sports injury, **13**:29
Hamate, diagnosis and treatment of, **3**:88
Hip, assessment and treatment of, **6**:108
Of lower extremity, pitfalls in diagnosing, **6**:108
Monteggia's, of elbow, diagnosis of, **5**:80
In neck trauma, **18**:33
Occult rib, as sign of child abuse, **16**:110
Orbital
  Assessment and treatment of, **9**:58
  Method for finding eye injuries associated with, **13**:83
Pelvic insufficiency, mimicking metastatic bone disease, **9**:77
Spinal
  False appearance of, on x-ray, **19**:96
  Spinal cord injury associated with, **9**:24
Stress
  Of foot and ankle, **13**:24
  Of pubic symphysis, **21**:173
  Of tibia, in child, **14**:214
Temporal bone, management of, **18**:19
Toe, trick for buddy taping, **21**:111
Upper extremity, pitfalls in diagnosing, **5**:63

Frostbite
In the homeless, **4**:43

Fumigants
Toxicity of, **3**:161

Fundus
Cherry-red spot on infant's, as sign of Tay-Sachs disease, **6**:103
Detecting disorders of, **17**:20
Examination, in diabetic retinopathy, **11**:89

Furosemide
For ascites, **18**:42
For hemorrhagic stroke, **14**:120

GH

Gait
In assessment of ankle injury, **1**:68
Disorders, in the elderly, treating, **8**:51
See also *Movement disorders*

Gallstones
Asymptomatic, in diabetics, nonsurgical approach to, **14**:49
Pancreatitis caused by, **2**:53
Symptomatic, surgical vs medical management of, **11**:131

Ganciclovir
For CMV infection in AIDS, **2**:38
For CMV retinitis, **16**:39

Gas
Natural, toxicity of, **3**:164
Toxic, inhalation injury from, **7**:53

Gastroenteritis
Appendicitis differentiated from, **9**:40
Diabetic ketoacidosis differentiated from, **20**:22
Electrolyte measurements unhelpful in, **14**:156

Gastrointestinal tract
Bleeding
  Anemia caused by, **14**:180
  Dexamethasone as cause of, **8**:48
  Upper
    Epistaxis caused by, **17**:35
    Management of, **18**:77
Disorders, as cause of chest pain in young adults, **2**:67
Effects of Mycoplasma pneumonia on, **14**:168
Effects of plant toxicity on, **11**:22

Gegenhalten
Of a limb, diagnosis of, **19**:22

Gentamicin
For penicillin-resistant enterococci, **16**:59

Giardiasis
Etiology and management of, **12**:77

Gingivitis
As predisposition to anaerobic pneumonia, **1**:34

Glaucoma
Danger of, with pupil dilation, **17**:20
Diagnosis and treatment of, **1**:111
  Acute, **9**:67

Glucagon
For insulin-induced hypoglycemia, **20**:34
For meat impaction, **21**:51

Glucose
CSF, in bacterial meningitis, **21**:41
For diabetic ketoacidosis, **8**:23
Intolerance, in malignant external otitis, **5**:54
See also *Tests*

Glycerin
For glaucoma, **1**:115

Glycerol
Intravenous, for ischemic stroke, **14**:121

Goiter
Thyroid carcinoma misdiagnosed as, **2**:91

Gold
Poisoning, diagnosis and treatment of, **8**:86

Gonococcemia
As cause of acute joint pain, **16**:83

Gonorrhea
Asymptomatic, treatment of, **13**:66
Benefits of routine testing for, **13**:64
Coinfection with Chlamydia, **16**:94
Differentiated from Chlamydia, in acute PID, **8**:33
Penicillin-resistant, ceftriaxone for, **11**:81

Gout
As cause of acute joint pain, **16**:80, 82
Crystal-induced bursitis in, **8**:71
Differentiated from deep vein thrombosis, **18**:94

Gouty tophi
In hands, diagnosis of, **1**:57

Grief
Normal process of, after child's death, **6**:94

Gumma
As sign of syphilis, **3**:106

Habit tic deformity
Of thumbnail, diagnosis, **15**:50

Hair
Dye, as cause of allergic contact dermatitis, **10**:98
Loss, as sign of thallium poisoning, **1**:40

Hallucinations
Signs of, in psychiatric interview, **14**:35

Hallux rigidus
From sports injury, **13**:30

Haloperidol
For sedation in multiple injuries, **9**:24

Hand
Abnormal pigmentation of, diagnosing, **16**:73
Anesthesia
Local, procedure for, **13**:107
Regional, Bier block for, **12**:73
Burned, sandwich splint for, **12**:66
Gouty tophi in, **1**:57
Knuckle pads, diagnosis and causes of, **9**:35
Ligament damage, in gamekeeper's thumb, **13**:115
Testing innervation of, after upper extremity trauma, **5**:70
Trauma, management of, **3**:79; **5**:87; **14**:131
Overuse, in musicians, **11**:125
See also *Finger*

Head
Bleeding, management of, **13**:71
ENT emergencies requiring referral, **18**:16
Trauma
Adult-onset seizures caused by, **1**:23
Cervical spine x-rays after, **17**:39
Predicting outcome in, **10**:37
Rapid hemostasis in, **6**:99

Headache
Cluster, prevention of, **14**:164
Differentiating vascular from tension, trick for, **8**:68
Legal implications of ED misdiagnosis of, **16**:40
Lumbar puncture as cause of
Caffeine for, **13**:126
Treatment protocol for, **2**:117
Prochlorperazine for, **12**:51
As sign of
Impending subarachnoid hemorrhage, **13**:105
Sinusitis, **21**:87, 89
Stroke, **14**:114
Temperomandibular joint inflammation as cause of, **19**:73
Trick for diagnosing type of, **2**:103
See also *Scalp*

Health care workers
Danger of HIV transmission to, **3**:170
Influenza immunization in, **17**:85

Hearing
Impairment, trick for eliciting history despite, **8**:68
Loss
In otitis media, **18**:18
Preventing, in bacterial meningitis, **8**:45
As sign of serious ear trauma, **18**:19

Heart
Block, from Lyme disease, **3**:64; **14**:54
Chronic bronchitis' effects on, **20**:72
Cocaine's effects upon, **21**:26
Disease
In the elderly, murmurs as signs of, **10**:21
Gait impairment as sign of, **8**:52
Pneumonia in, **7**:33
Premature, misdiagnosis of, **12**:99
Rheumatic, influenza immunization in, **17**:85
Screening for silent ischemia in, **20**:97
Syncope caused by, **14**:40
Failure
Associated with elevated liver enzymes, **6**:69, 73
Congestive, emergent hypertension in, **8**:95
As risk factor for DVT, **4**:88
X-ray diagnosis of, **17**:124
Influenza's effects on, **17**:75
Injury
From high-voltage electrical shock, **13**:86
From penetrating chest trauma, **20**:82
Mycoplasma pneumonia's effects on, **14**:167
Sounds, in differentiating angina from MI, **15**:61
See also specific conditions

Heavy metal
Poisoning, diagnosis and treatment of, **8**:81
Danger of, in button battery ingestion, **17**:42

Heel
Black, diagnosis of, **13**:111
Child's, apparent osteochondriasis of, on x-ray, **5**:125
Sports injuries to, **13**:18

Hemangioma
Subglottic, congenital, airway obstruction from, **7**:63

Hematemesis
Management of, **18**:83

Hematoma
Pleural effusion as sign of, **11**:101
Potential for, in arterial puncture, **21**:72
Retroperitoneal, diagnosis and treatment of, **3**:147
Subungual, of toe, **13**:30

Hematopoiesis
Abnormal, heavy metal toxicity as cause of, **8**:81

Hematuria
As sign of appendicitis, **9**:40

Hemiballismus
Diagnosis and treatment of, **19**:33

Hemiparesis
Nonketotic hyperglycemia as cause of, **21**:37
As sign of stroke, **14**:112

Hemiplegia
As sign of stroke, **14**:112

Hemolysis
Anemia caused by, **14**:179
In lead poisoning, **8**:88

Hemoperitoneum
As sign of splenic rupture, **1**:76

Hemophilia
Diagnosis and treatment of, **8**:146
Risk of HIV transmission in, **3**:177

Hemoptysis
From cerebral air embolism, **10**:66

Hemorrhage
Cerebral
Emergent hypertension associated with, **8**:94
Stroke caused by, **14**:112
Intraperitoneal, cardiac tamponade caused by, **8**:135

continued

Middle- and inner-ear, in barotrauma, **10**:62
Retinal, at high altitudes, **5**:35
Retrobulbar, management of, **9**:58
Scalp, controlling, **13**:71
Subarachnoid
Headache as warning sign of, **13**:105
Legal implications of ED misdiagnosis of, **16**:40
Stroke caused by, **14**:112
Vitreous
Diagnosis of, **17**:23
Sudden loss of vision caused by, **20**:66
See also *Bleeding; Epistaxis;* specific sites

Hemorrhoids
Tying off, trick for, **20**:57

Hemostasis
After arterial puncture, technique for, **21**:69
See also *Bleeding; Hemorrhage; Resuscitation*

Hemostats
To control scalp bleeding, **13**:75

Hemotympanum
As sign of epistaxis from aspirin therapy, **8**:129
Spontaneous epistaxis as cause of, **5**:63

Heparin
For DVT, **13**:154
Low-dose, **4**:89
For interstitial cystitis, **11**:154
For ischemic stroke, **14**:120
As MI prophylaxis, in unstable angina, **11**:74
For pulmonary embolism, **7**:50
Role of, in bleeding disorders, **8**:158
For thrombophilia, **6**:52

Hepatitis
A
Cholestatic, **16**:135
History and diagnosis of, **16**:131
Prophylaxis, **16**:135
Alcoholic
Differentiated from acetaminophen overdose, **15**:82
Methylprednisolone for, **20**:90
B
Acute joint pain caused by, **16**:84
History and diagnosis of, **16**:124
Sequelae to, **16**:131
D, as sequela to hepatitis B, **16**:131
Differentiating forms of, **10**:33
Isoniazid-induced, **11**:67
Non-A, non-B, history and diagnosis of, **16**:135
Recurrent, as risk factor for Pneumocystis pneumonia, **9**:72
From sustained-release niacin, **20**:50
Transmission, from needle sticks, **3**:177; **16**:12
Treatment, **16**:136
Viral, diagnosis and treatment of, **16**:124

Hepatotoxicity
Niacin as cause of, **20**:50

Herbicide
Poisoning, **3**:161

Hernia
Urinary retention associated with, misdiagnosis of, **13**:118

Herpes
In AIDS, **2**:36
Keratitis, diagnosis of, **9**:67
Zoster oticus, diagnosis and treatment of, **3**:76

Hip
Pain
Arthritis as cause of, **8**:52
Calcific tendinitis as cause of, **9**:97
Trauma, pitfalls in diagnosing, **6**:108

Histamine
Role in anaphylaxis, **16**:51

Histiocytosis X
Diagnosis and treatment of, **19**:64

HIV
Danger of transmission to health care workers, **3**:170
Endocarditis associated with, **8**:44
Infection, as risk factor for neurosyphilis, **10**:91
Precautions against transmission of, **3**:173
See also *AIDS*

Hives
See *Urticaria*

Hoarseness
As sign of laryngeal cancer, **4**:62

Hodgkin's disease
Cervical adenopathy caused by, **4**:66
Elevated liver enzymes associated with, **6**:73
Unexplained fever caused by, **5**:114

Homeless patients
Health care of, **4**:21

Hormones
For management of vaginal bleeding, **9**:92
Thyroid, measuring levels of, **13**:61
Thyrotropin releasing, in motor neuron disease, **19**:21

Houseplants
Toxicity from, signs and treatment of, **11**:48

Human immunodeficiency virus
See *HIV*

Human papillomavirus
Infection in men, diagnosis and treatment of, **13**:121

Humerus
Avulsion of greater tuberosity, assessment and treatment of, **5**:67
Fracture, diagnosis of, **5**:85

Hyalosis
Asteroid, diagnosis of, **17**:23

Hydralazine
For control of blood pressure after stroke, **14**:115
For emergent hypertension, **8**:94

Hydrocephalus
Gait impairment as sign of, **8**:53

Hydrocortisone
For anaphylaxis, **16**:58

Hydrodistention
Bladder, for interstitial cystitis, **11**:154

Hydrogen sulfide
Inhalation injury from, **3**:169; **7**:62

Hydroids
Fire, envenomation by, **12**:28

Hymenoptera stings
As cause of anaphylaxis, **16**:52

Hypercapnia
Chronic bronchitis as cause of, **20**:75

Hypercholesterolemia
Niacin for, **20**:50

Hyperglycemia
In diabetic ketoacidosis, **8**:22
Nonketotic, movement disorders associated with, **21**:37

Hyperkalemia
As sign of diabetic ketoacidosis, **8**:22

Hypersympathetic state
Cocaine as cause of, **21**:26

Hypertension
In cocaine intoxication, treatment of, **21**:34
Effect of, on ocular fundus, **17**:29
Emergent vs urgent, management of, **8**:92
In the homeless, causes and treatment of, **4**:38
Malignant, management of, **8**:98
Pulmonary, chronic bronchitis as cause of, **20**:72
As risk factor for diabetic retinopathy, **11**:89
With stroke, treatment of, **14**:115, 122

Hyperthermia
In the homeless, **4**:43
Malignant, risk of, in nitrous oxide use, **3**:124

Hyperthyroidism
Testing for, **13**:61

Hyperventilation
With chest pain, in young adults, **2**:67
Danger of diagnosing, **14**:129
MI as cause of, **11**:77
As sign of acidosis in diabetic crisis, **20**:22

Hypervolemia
In ketoacidosis with kidney dysfunction, **20**:26

continued on page 137

Hyphema
Diagnosis of, **1**:107
Significance and management of, **9**:55

Hypoglycemia
Chlorpropamide as cause of, **6**:34; **10**:80; **12**:9 (letter)
Diabetic, coma caused by, **8**:32
Emergent, recognition and treatment of, **20**:32

Hypoglycorrhachia
As sign of bacterial meningitis, **21**:41

Hyponatremia
False, lab inaccuracy as cause of, **12**:87
Thiazide as cause of, **11**:162

Hypotension
In anaphylaxis, treatment of, **16**:51
In coelenterate envenomation, **12**:30
In diabetic ketoacidosis, **8**:22
MAST suit for, inadvisability of, **20**:86
Orthostatic, as possible cause of syncope, **14**:40
In toxic shock syndrome, **8**:122

Hypothermia
In acute mountain sickness, **5**:23
For CO-induced neuropathy, **7**:54
In the homeless, **4**:43

Hypothyroidism
Testing for, **13**:61

Hypovolemia
In diabetic ketoacidosis, **8**:24
See also *Resuscitation*

Hypoxemia
As sign of ARDS, **7**:67

Hysteria
Diagnosis of, trick for, **10**:31

Ichthyosis vulgaris
Diagnosis and treatment of, **2**:41

Imidazole
For candidiasis, **20**:128

Immobilization
After ankle injury, **1**:69
Cervical spine, optimal method for, **9**:24

Immunization
BCG, positive TB tests after, **21**:66
In chronic bronchitis, importance of, **20**:71
Hepatitis A, development of, **16**:135
Hepatitis B, **16**:126
  In neonates, **10**:36
Influenza
  Annual need for, **17**:84
  For cardiac patients, **7**:40
Measles, new recommendations for, **17**:103
Pneumococcal, for cardiac patients, **7**:40
Recording of, trick for, **10**:31
Remembering dates of, trick for, **6**:96

Immunocompromised patients
Bacterial arthritis in, **16**:82
CMV retinitis in, screening for, **16**:37
Dangers to, from corticosteroid therapy for COPD, **17**:114
Fungal infections in, **15**:18
Increased risk for melanoma in, **16**:109
Influenza in, **17**:64
Risk of listeriosis in, **15**:31
Risk of septic bursitis associated with, **8**:71
Tuberculosis prophylaxis in, **21**:63
See also *AIDS*

Immunotherapy
As cause of anaphylaxis, **16**:52

Indomethacin
For gout or pseudogout, **16**:82

Infants
Abdominal obstruction in, diagnosis of, **10**:42
Abused, diagnosis of, in ED, **16**:110
Acropustulosis in, diagnosis of, **17**:90
Airway abnormality in, congenital, **7**:63
Asthma in, caused by chronic lung disease, **11**:120
Boric acid ingestion in, **1**:85
Conjunctivitis in, cause and treatment of, **1**:100
Glaucoma in, congenital, **1**:115
Intubation of, **19**:81
Methemoglobinemia in, from ammonia poisoning, **3**:164
Removal of toy lodged in mouth of, **16**:110
Risk of listeriosis in, **15**:31
Sternocleidomastoid tumor in, diagnosis of, **8**:105
See also *Children; Neonates*

Infarction
Bowel, diabetic ketoacidosis caused by, **8**:23
Cerebral
  Diabetic ketoacidosis caused by, **8**:23
  Error in diagnosing, **21**:167
See also *Myocardial infarction*

Infection
Back pain caused by, **11**:164
In cancer, as cause of fever, **21**:55
CNS, *Listeria monocytogenes* as cause of, **15**:32
Colon, differentiated from irritable bowel syndrome, **16**:70
As complication to chronic bronchitis, **20**:75
Corneal
  Extended-wear contact lenses as cause of, **9**:67
  Red eye caused by, **1**:103
In development of ARDS, **7**:68
Diabetic ketoacidosis caused by, **8**:23
In the elderly, without fever, diagnosis of, **18**:91
ENT, requiring referral, **18**:16
Enterovirus, differentiated from Lyme disease, **3**:62
Focal, toxic shock syndrome caused by, **8**:119
Foot, likelihood of, after nail puncture wound, **21**:81
Fungal, in the immunocompromised, **15**:18
After high-voltage electrical injury, **13**:94
Interstitial lung disease caused by, **19**:63
Intracranial, as complication to sinusitis, **21**:100
In mouth wounds, prophylaxis against, **19**:89
Neck mass caused by, **4**:61, 70
Opportunistic
  In AIDS, **2**:25
  With long-term corticosteroid treatment of COPD, **17**:114
Orbital, as complication to sinusitis, **21**:97
Pericarditis caused by, **8**:131
Pulmonary
  Anaerobic, **1**:33
  Recurrent, as sign of dysphagia, **1**:54
"Space," airway compromise from, **18**:32
Super-, in influenza, **17**:70
Unexplained fever caused by, **5**:108
Upper respiratory
  As precursor to sinusitis, **21**:87
  Resemblance of measles to, **17**:99
Urinary tract, differentiated from interstitial cystitis, **11**:149
Urine dipsticks to detect, reliability of, **19**:41
Viral, resemblance to hepatitis, **11**:67
Yeast, in vagina, diagnosis and treatment of, **20**:127
See also specific infections

Infertility
PID as cause of, **8**:33

Influenza
Acute bronchitis associated with, **8**:113
Cardiac effects of, **17**:75
Deadly effects of, diagnosis and treatment of, **17**:61
Immunization against, **17**:84
Pneumonia after, treatment for, **7**:84

Ingestion
Of button batteries, management of, **17**:42; **21**:51
Of coins, by college students, management of, **11**:200; **21**:51
See also *Poisoning*

Inhalation
Injury, **3**:164; **7**:59
Therapy, trick for improving, **2**:103

Insect repellants
For malaria prophylaxis, **13**:144

Insecticide
Poisoning, **3**:152

Insects
See *Bites; Stings*

continued

Insulin
For diabetic crises, **20**:24, 32
For diabetic ketoacidosis, **8**:24
Fluctuations, as risk factor for diabetic retinopathy, **11**:89
For homeless diabetics, **4**:35
Lack of, diabetic ketoacidosis caused by, **8**:23
For nonketotic hyperglycemic movement disorders, **21**:38

Interferon
For hepatitis, trials of, **16**:136

Intrauterine device
As risk factor for PID, **8**:37

Intubation
As cause of lung atelectasis, **20**:132
Endotracheal
Of adults, procedure for, **14**:81
For anaphylaxis, **16**:58
Apparent tube misplacement in, **16**:137
For ARDS, **7**:70
Of children, **19**:81
Equipment for, mechanics and maintenance of, **12**:91
Errors in, **15**:91
Evaluation before, to anticipate problems, **10**:107
Identifying landmarks for, **8**:171
Of kyphoscoliotic patient, **5**:45
As risk factor for sinusitis, **21**:87
Tests to check tube placement after, **17**:93
Esophageal, for feeding, apparent tube misplacement in, **6**:132
Main-stem, discovering and correcting complications of, **17**:94
Nasogastric
In diagnosis of GI bleeding, **17**:35; **18**:33
In herniated stomach, x-ray appearance of, **18**:98
For perforated duodenal ulcer, **14**:143
For pyloric stenosis in infant, **10**:42
As risk factor for sinusitis, **21**:87
Nasotracheal
As alternative to oral intubation, **21**:68
Oral, in cervical spine injuries, dangers of, **21**:68

Intussusception
Ileocolic, in child, **8**:129

Ipecac
Activated charcoal preferred to, after moderate overdose, **14**:154
For boric acid ingestion, **1**:85
Effectiveness of, in theophylline overdose, **15**:87

Ipratropium bromide
For acute asthma, **7**:28
For chronic asthma, **7**:93
For COPD, **7**:93

Iritis
Diagnosis and treatment of, **1**:107; **9**:67

Iron
Deficiency
In adolescent athletes, **17**:51
Anemia caused by, **14**:179

Irrigation
Ear, using tap water, as cause of malignant external otitis, **5**:58
Eye, for chemical burns, **9**:54
For marine animal envenomation, **12**:30, 36, 38
Without syringe, trick for, **6**:96

Ischemia
Cerebral, as cause of stroke, **14**:112
Cerebrovascular, as cause of vertigo, **16**:113
Of fingers, in hand injuries, **14**:132
Myocardial
Cocaine as cause of, **21**:31
Mechanism of, **15**:59
Silent, screening for, **20**:97
Tissue, as cause of cocaine-induced rhabdomyolysis, **6**:100

Isoetharine
Nebulized, for acute asthma, **7**:93

Isoniazid
Hepatotoxicity of, **11**:67
For tuberculosis, **14**:101
In homeless patients, **4**:27
For prophylaxis, **21**:63

Isoproterenol
For acute asthma, **7**:25
Intravenous, **7**:94

Itraconazole
For fungal infection in the immunocompromised, **15**:26

Jarisch-Herxheimer reaction
After treatment for syphilis with PID, **8**:37

Jaundice
As sign of hepatitis, **16**:126
As sign of pyloric stenosis in infants, **10**:45

Jellyfish
Envenomation by, **12**:28

Joint
Damage to, in hand injuries, **14**:133
Metacarpophalangeal
Involvement of, in gout, **16**:82
Stability of, in gamekeeper's thumb, **13**:116
Pain
Acute attack of, diagnosis of, **16**:80
As symptom of decompression sickness, **10**:71
Sternoclavicular, dislocated, diagnosis and reduction of, **5**:66
Temporomandibular
Inflammation of, **19**:73
Pain in, in malignant external otitis, **5**:54
See also specific joints

Kaolin
For traveler's diarrhea, efficacy of, **12**:85

Kawasaki disease
Differentiated from
Measles, **17**:99
Toxic shock syndrome, **8**:123

Keratitis
Herpes simplex, diagnosis of, **9**:67
Ultraviolet, diagnosis and treatment of, **9**:63

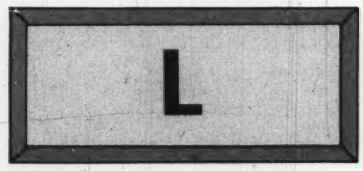
Ketoacidosis
Diagnosis and treatment of, **8**:20; **20**:20
Misdiagnosed in adolescent, **20**:81
Misdiagnosed as asthma, **15**:27
See also *Diabetes*

Ketoconazole
For candidiasis, **20**:128
For fungal infection in the immunocompromised, **15**:20

Kidney disease
Malignant hypertension as cause of, **8**:99
See also *Renal failure*

Knee
Bursitis in, **8**:71
Dermatitis herpetiformis on, **16**:74
Housemaid's, diagnosis and treatment of, **8**:71
Injured
Assessment and treatment of, **3**:127
Pitfalls in diagnosing, **6**:111
Joint, landmarks, **3**:128
Pain, in child, x-ray diagnosis of, **14**:213
Runner's, diagnosis and treatment of, **3**:136
See also *Patella*

Kyphoscoliosis
As cause of difficult intubation, **5**:45



Labetalol
In cocaine intoxication, **21**:34
For emergent hypertension from drug overdose, **8**:98
For malignant hypertension, **8**:99

Labor
Premature, listeriosis as cause of, **15**:32

Lactic dehydrogenase
Serum, measurement of, to diagnose MI, **15**:64

Lactose
Intolerance, role of, in irritable bowel syndrome, **16**:70

Lactulose
For constipation from irritable bowel syndrome, **16**:72

Laparoscopy
For diagnosis of pelvic pain in women, **6**:24
For PID, **6**:31; **8**:33

Laparotomy
Exploratory, for suspected appendicitis, **9**:40
For unexplained fever, **5**:119

Laryngoscopy
Fiberoptic, for inhalation injury, **7**:59
Indirect, trick for unfogging mirror during, **16**:86
Proper technique for, for oral intubation of adults, **14**:81

Larynx
Anatomy and action of, for intubation, **8**:171
Disruption of, from neck trauma, **18**:33

Lavage
Bronchoalveolar, for diagnosis of Pneumocystis pneumonia, **9**:74
Gastric, for upper GI bleeding, **18**:83
Peritoneal
For perforated duodenal ulcer, **14**:153
For splenic injury, **1**:76
Vs ultrasonography for detecting abdominal injury, **15**:45

Laxatives
Abuse of, in irritable bowel syndrome, **16**:72

L-dopa
For Parkinson's disease, **19**:23

Lead
Poisoning, diagnosis and treatment of, **8**:86

Leg
DVT in
Dangers of embolization from, **13**:151
Misdiagnosed as gout, **18**:94
Pain in, as symptom of atheromatous embolism, **21**:74
Pseudoaneurysm in, after blunt trauma, **13**:150
Thrombophlebitis in child's, diagnosis of, **3**:75
Trauma
From a fall, **14**:209
Pitfalls in diagnosing, **6**:108
As risk factor for DVT, **4**:88
See also *Foot; Knee*

Legionnaires' disease
Diagnosis and treatment of, **14**:168

Leptospirosis
Differentiated from toxic shock syndrome, **8**:122

Leukemia
Unexplained fever caused by, **5**:114

Leukocytosis
As sign of infection in afebrile elderly patients, **18**:91
As sign of neurosyphilis, **10**:91

Leukopenia
As sign of ehrlichiosis, **14**:102
As sign of toxic epidermal necrolysis, **14**:68

Lice
In the homeless, **4**:22

Lichen planus
Diagnosis and treatment of, **19**:36

Lidocaine
For arrhythmia prophylaxis in transport of MI patients, **16**:123
For local anesthesia, tricks for using, **8**:68
For wide QRS tachycardia, **9**:44
For wrist block, **13**:107

Ligation
Caval, for pulmonary embolism, **7**:51
To control scalp bleeding, **13**:75
Endoscopic, for esophageal bleeding, **6**:37
Uses of innominknot for, **20**:57

Limbs
Movement disorders of, **19**:22
See also *Arm; Leg*

Lindane
For scabies, in homeless patients, **4**:23

Listeriosis
Diagnosis and treatment of, **15**:31, 44

Lithium
For cluster headache prophylaxis, **14**:164

Lithotripsy
Shock-wave
For gallstones in diabetics, **14**:52
For symptomatic gallstones, **11**:131, 135

Liver
Cancer, risk of, with hepatitis, **16**:131
Disease
Alcohol-induced, corticosteroid therapy for, **20**:90
Managing ascites from, **18**:42
Rickets caused by, **7**:73
Enzymes, asymptomatic elevations of, **6**:69
Surgery, pleural effusion as complication, **11**:96
Toxicity
From acetaminophen, **15**:82
From niacin, **20**:50
See also *Hepatitis*

Lobectomy
Anterior, for seizures, risks vs benefits of, **18**:58

Loperamide
For diarrhea from irritable bowel syndrome, **16**:72
For traveler's diarrhea, **12**:85, **18**:9 (letter)

Lorazepam
For pediatric febrile seizures, **11**:197

Lou Gehrig's disease
See *Sclerosis, Amyotrophic lateral*

Lumbar puncture
For acute weakness, **4**:110
For early syphilis in AIDS patients, **10**:91
For febrile seizures, controversy over, **11**:192
Headache caused by, treatment of, **2**:117
Caffeine for, **13**:126
For neurosyphilis, **3**:114
For possible subarachnoid hemorrhage, **13**:105
For suspected stroke, **14**:116

Lung
Bird breeder's, diagnosis and treatment of, **19**:63, 71
Burst, diving ascent barotrauma as cause of, **10**:64
Cancer
Differentiated from round pneumonia, **2**:54
Superior vena cava syndrome caused by, **15**:72
Diffusing capacity of, measurement of, **13**:41
Disease
Chest pain in young adults caused by, **2**:67
Chronic, of the newborn, asthma caused by, **11**:120
Obstructive, seen on spirometry, **13**:36
Embolism in, from DVT, **13**:151
Injury
In ARDS, **7**:67
From toxic gas inhalation, **3**:164; **7**:53
Interstitial disease of, diagnosis and treatment of, **19**:63
Opportunistic infections of, in AIDS, **9**:76
Rapid reexpansion of, dangers of, **10**:80
Testing function of, **7**:60; **13**:35; **19**:63
See also specific diseases

Lye
Ingestion by children, **4**:71

Lyme disease
Cardiac manifestations of, **14**:54
Diagnosis and treatment of, **3**:55
Differentiated from ehrlichiosis, **14**:102
Efficacy of prophylaxis against, **10**:49
Tests to diagnose, **14**:56
Unreliability of, **13**:46

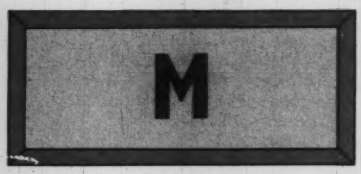
Lymphadenopathy
Palpation for, in suspected lymphoma, **8**:146
As sign of secondary syphilis, **3**:107
As sign of sinusitis, **21**:88

Lymphangioleiomyomatosis
Diagnosis and treatment of, **19**:64

Lymphedema
In decompression sickness, **10**:70

Lymphoma
As cause of superior vena cava syndrome, **15**:69
Cervical adenopathy caused by, **4**:66
Diagnosis of, **18**:146
See also *Hodgkin's disease*

continued



Macrocytosis
In assessment of anemia, **14**:184
Inverse relationship to cobalamin level, **11**:102

Macula
Disorders of, **17**:24

Maggots
Infesting indwelling Foley catheter, trick for removing, **18**:41
In wounds, benefits of, **13**:78; **18**:41; **21**:111

Magnesium sulfate
For perforated duodenal ulcer, **14**:150
For seizures in eclampsia, **8**:94

Magnetic resonance imaging
For back pain, efficacy of, **11**:164
For cervical spine injury, **9**:28
For otitis media, **18**:19
For suspected stroke, **14**:116
For temporomandibular joint disorders, **19**:74

Malaria
Acute, management of, **13**:142
Diagnosis and treatment of and prophylaxis for, **13**:129

Malleolus
Fracture of, diagnosis and treatment of, **6**:121

Malnutrition
Drug-induced, in the elderly, **4**:56
In the homeless, **4**:28

Malocclusion
From temporomandibular joint inflammation, **19**:73

Malpractice
See *Medicolegal issues*

Man-of-war
Envenomation by, **12**:28

Mannitol
For hemorrhagic stroke, **14**:120
For retinal artery occlusion, **20**:65

Manometry
Esophageal, for variceal bleeding, **6**:37

Marine animals
Envenomation by, **12**:26
Prevention of, **12**:41
See also specific animals

Mast cell
In anaphylaxis, **16**:51
Inhibitors, for acute asthma, **7**:30
In interstitial cystitis, **11**:151

MAST suit
For hypotension, inadvisability of, **20**:86

Mastocytosis
In interstitial cystitis, **11**:151
Systemic, differentiated from anaphylaxis, **16**:56

Measles
Diagnosis and treatment of, **17**:97

Meat impaction
Diagnosis and treatment of, **21**:46

Medicolegal issues
Battered women, aid to, **11**:107
Casual presuit conversations, safety of, **21**:105
Certification of drug-free status, **13**:95
Changing counsel during malpractice case, **10**:55
Confidentiality, **6**:125
Consent for treatment, **2**:8; **7**:11 (letter)
Delay in treatment, responsibility for, **20**:35
Diagnoses, accurate recording of, **18**:51
"Do not resuscitate" orders, **6**:53
ED triage responsibility, **16**:40
In facial trauma management, **18**:30
Frivolous suits, **17**:11 (letter)
Liability of physicians on hospital committees, **14**:74
Release of information, **6**:125
Restraint in the ED, **8**:169
Transfer of critically ill patients, **2**:71

Mefloquine
For malaria prophylaxis, **13**:144

Melanoma
Choroidal, diagnosis of, **17**:30
Malignant
Diagnosis of, **17**:90
Dysplastic nevi as precursor to, **16**:104

Melena
As sign of GI bleeding, **18**:77

Memory
Disorders, signs of, in psychiatric interview, **14**:35

Meningitis
Aseptic
In Lyme disease, **3**:62
In secondary syphilis, **3**:107
Bacterial
Delay in treatment of, implications of, **20**:47
Dexamethasone for, **8**:45
Shortcut to diagnosis of, **21**:41
Cryptococcal, in AIDS, **2**:35
Listeria monocytogenes as cause of, **15**:32
Meningoccocal, differentiated from toxic shock syndrome, **8**:122
Risk of, in children with febrile seizures, **11**:190
Strokelike symptoms caused by, **14**:116
After temporal bone fracture, **18**:20

Meningococcemia
Differentiated from toxic shock syndrome, **8**:122

Menisci
Assessment of, in injured knee, **3**:133

Menstruation
Anemia caused by, **14**:180
Anovulatory, excessive or irregular bleeding in, **9**:86
Hemorrhagic, as sign of bleeding disorder, **8**:145

Mental status
Altered
As danger sign in varicella, **7**:63
In ear or facial trauma, **18**:20
In the elderly, drugs as cause of, **4**:55
Restraints in, need for, **8**:169
As sign of lead poisoning, **8**:86
As sign of stroke, **14**:112
Determination of, in psychiatric interview, **14**:29

Metaproterenol
Nebulized, for acute asthma, **7**:93

Methyl bromide
Poisoning, on the farm, **3**:164

Methyl *tert*-butyl ether
For gallstone dissolution, **11**:138

Methylprednisolone
For alcoholic hepatitis, **20**:90
For COPD, **17**:116
Efficacy of, in bacterial meningitis, **8**:48

Methylxanthines
For acute asthma, **7**:25, 93

Methysergide
For cluster headache prophylaxis, **14**:164

Metronidazole
For bacterial vaginosis, **20**:121
For trichomoniasis, **20**:126

Miconazole
For candidiasis, **20**:128

Microcytosis
In assessment of anemia, **14**:179

Miscarriage
Risk factors for, **9**:90

Mitral valve prolapse
As cause of angina in young adults, **2**:66
In the elderly, auscultatory diagnosis of, **10**:23

Moles
Changes in, as precursor to melanoma, **16**:104

Monitoring
Holter
To determine cause of syncope, **14**:41
To measure cardiac effects of influenza, **17**:76

continued

Professional Use Information

CARAFATE®
(sucralfate) 1gm Tablets

BRIEF SUMMARY

CONTRAINDICATIONS
There are no known contraindications to the use of sucralfate.

PRECAUTIONS
Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be non-systemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

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INDEX 1989

Mononucleosis
Differentiated from measles, **17**:99
Differentiated from toxoplasmosis, **17**:36

Mosquitoes
As transmitters of malaria, **13**:128

Motility
Related to irritable bowel syndrome, **16**:69

Mouth
Canker sores in, diagnosis and treatment of, **9**:35
Lesions in newborn, diagnosis of, **18**:67
Wounds, infection prophylaxis in, **19**:89

Movement disorders
Diagnosis of, **19**:21
In the elderly, as cause of falls, **8**:51
Nonketotic hypoglycemia as cause of, **21**:37

Mucokinetics
For pneumonia, utility of, **7**:88

Mucormycosis
In the immunocompromised, **15**:18
In sinusitis, **21**:88

Murmurs
Heart, in the elderly, interpretation of, **10**:21

Mushrooms
Toxicity from, signs and treatment of, **11**:62

Musicians
Occupational injuries in, **11**:125
Performance anxiety in, management of, **19**:29

Myalgia
As sign of cocaine-induced rhabdomyolysis, **6**:102

Myasthenia gravis
Weakness caused by, **4**:102, 105

Mycobacteriosis
As cause of wasting in AIDS, **2**:35

Mycoplasma
Extrapulmonary manifestations of, **14**:167
Pneumonia, diagnosis and treatment of, **14**:166

Myelography
For cervical spine injury, **9**:28

Myelopathy
Spinal cord, from nitrous oxide abuse, **3**:121

Myocardial infarction
Cocaine as cause of, **21**:31
Differentiated from pericarditis by ECG, **8**:135
Differentiated from unstable angina, **15**:59
Emergent hypertension in, **8**:95
Heparin prophylaxis for, **11**:74
Hyperventilation as cause of, **11**:77
Serial enzyme measurements to diagnose, **14**:159
Silent, with diabetic ketoacidosis, **8**:23
Silent ischemia as warning sign of, **20**:97
Sudden loss of vision as precursor to, **20**:66
Transporting patients with, benefits of, **16**:119
Ventricular tachycardia after, **9**:44
Viral myocarditis as cause of, **1**:89

Myocarditis
Viral, as cause of MI, **1**:89

Myoclonus
Diagnosis and treatment of, **19**:31
Nonketotic hyperglycemia as cause of, **21**:Bi

Myopathy
Transient, influenza-related, **17**:72

Myringotomy
For otitis media, **18**:19

Nadolol
For tremor from performance anxiety, **19**:29

Nafcillin
With chloramphenicol, for otitis media, **18**:18
For endocarditis, **8**:42
For toxic shock syndrome, **8**:120

Naproxen
For neoplastic fever, **21**:59

Narcosis
Nitrogen, diagnosis and treatment of, **10**:69

Nausea
With dizziness, diagnosis of, **18**:71

Neck
Mass
Diagnosis and treatment of, **4**:61
Sternocleidomastoid tumor as cause of, in infant, **8**:105
Pain
Absence of, as contraindication to x-rays after trauma, **17**:39
Immediate onset of, as sign of fracture, **9**:25
Stiffness, as sign of hemorrhagic stroke, **14**:114
Trauma
Assessment and management of, **9**:22
X-ray diagnosis of, **19**:95
Vein filling in, as sign of dehydration, **20**:23

Needlestick injury
Hepatitis transmission in, **3**:177; **16**:124
HIV infection from, **3**:173

Neonates
Dental lamina cysts in, **18**:68

Red eye in, diagnosis and treatment of, **9**:67
See also *Infants*

Nephrotoxicity
Aminoglycosides as cause of, **2**:92

Nerves
Damage to, in hand injuries, **14**:133
Entrapment syndromes of, in musicians, **11**:129
Optic, atrophy of, **17**:23

Netilmicin
As alternative to aminoglycosides, **2**:92

Neuritis
Optic, as cause of sudden loss of vision, **9**:69

Neuroleptics
As cause of tardive chorea, **19**:32

Neuropathy
CO inhalation as cause of, **7**:54
Cranial, in malignant external otitis, **5**:53
In dysbaric diving injuries, **10**:66
In gait impairment in the elderly, **8**:52
Peripheral
  Fumigant toxicity as cause of, **3**:164
  Heavy metal poisoning as cause of, **8**:86
  Thallium poisoning as cause of, **1**:40
Sensorimotor, nitrous oxide as cause of, **3**:118

Neurosyphilis
Diagnosis and treatment of, **3**:114
Early appearance of, in AIDS patients, **10**:91

Neutropenia
As risk factor for fungal infection in the immunocompromised, **15**:18

Nevus
Dysplastic, as precursor to malignant melanoma, **16**:104
Facial, dermatosis papulosa nigra as cause of, **11**:167
Sebaceus of Jadassohn, diagnosis of, **5**:59

Niacin
To lower cholesterol, risks vs benefits of, **20**:50

Nicardipine
For ischemic stroke, **14**:121

Nifedipine
For emergent hypertension in stroke, **8**:94
For unstable angina, **3**:45; **8**:100

Nitrates
For cocaine-induced cardiac ischemia, **21**:35

Nitrites
As antidote for cyanide poisoning, **9**:45

Nitrogen dioxide
Inhalation injury, **3**:164; **7**:60

Nitroglycerin
For emergent hypertension, **8**:95
For unstable angina, **3**:40
For venodilation before venipuncture, **6**:96

Nitroprusside
For emergent hypertension, **8**:92

Nitrous oxide
Abuse, differential diagnosis of, **3**:117
Anesthetic advantages of, **3**:117
Hazards, **3**:118, 121

N-methyl carbamate
Poisoning, **3**:152

Nodules
Bohn's, in newborn, **18**:68

Nose
Traumatic injury to, implications of, **18**:16
Foreign body in, in child, trick for removing, **16**:86

Nosebleed
See *Epistaxis*

Numbness
Facial or extremity, as sign of stroke, **14**:112

Nursing homes
Incidence of pneumonia in, **7**:77
Influenza immunization in, **17**:85

Nystagmus
In diagnosis of dizziness, **18**:74

Nystatin
For fungal infection in the immunocompromised, **15**:20

Obesity
Elevated aminotransferase associated with, **6**:70

Obstruction
Airway
  Congenital subglottic hemangioma as cause of, **7**:63
  On pulmonary function testing, **13**:35
  Risk of, in intubation of children, **19**:83
Cystic duct, diagnosis and treatment of, **11**:136
Gastric outlet, in infant, pyloric stenosis as cause of, **10**:42
Ostial, in sinusitis, **21**:87
Vena cava, diagnosis of, **15**:69

Occlusion
Central retinal artery
  Emergent treatment of, **20**:60
  Sudden vision loss caused by, **9**:69
Cerebral, thromboembolic, as cause of stroke, **14**:112
Retinal vein, sudden vision loss caused by, **20**:66
Of small arteries, from atheromatous embolism, **21**:73
Vascular
  In decompression sickness, **10**:70
  In ocular fundus, diagnosis of, **17**:29
See also *Embolism*

Olecranon
Bursitis in, **8**:71

Ophthalmia
Sympathetic, following eye laceration, **9**:56

Ophthalmoscopy
For CMV retinitis screening in the immunocompromised, **16**:37
For detection of
  Diabetic retinopathy, **11**:89
  Fundus disorders, procedure, **17**:20
In ocular emergencies, **9**:52
In sudden vision loss, **20**:60

Organ donation
From child, requesting parents' permission for, **6**:82

Organophosphate
Poisoning, **3**:152

Orthotics
For instrument-related injury in musicians, **11**:139
For knee injury, **3**:136

Os acromiale
X-ray diagnosis of, **3**:184

Osteochondritis dissecans
Ankle injury as cause of, **1**:72

Osteomyelitis
Diagnosis of, in child's painful elbow, **6**:103

Osteoporosis
As cause of pubic insufficiency fracture, **21**:173

Otitis
External, similarity to ear canal squeeze, **10**:62
  Malignant, diagnosis and treatment of, **5**:53
Media
  Emergent, recalcitrant, or complicated, **18**:16, 33
  With influenza, **17**:72
  Serous, with sinusitis, **21**:88

Otorrhea
Purulent, in malignant external otitis, **5**:54

Otoscopy
Of child, trick for, **6**:96

Ototoxicity
Aminoglycosides as cause of, **2**:92

Ovaries
Abscess in, as complication of PID, **8**:33
Cancer of, in the elderly, **16**:28
Torsion of, **6**:33

Oxygen
For acute mountain sickness, **5**:26
For children, trick for administering, **2**:103
For chronic bronchitis, **20**:72
Hyperbaric
  For brown recluse spider envenomation, **14**:39
  For CO poisoning, **7**:54
    In pregnancy, **12**:46

continued

Impairment of lung defenses by, **7**:34
For interstitial lung disease, **19**:71
Methods of delivery, in COPD, **7**:94
For pneumonia, **7**:85
Saturation, in CO poisoning, **7**:54; **12**:9 (letter)
For treatment of decompression sickness, **10**:75

PQR

Pacemaker
Temporary, for Lyme carditis, **14**:56
Wire, for wide QRS tachycardia, **9**:44

Paget's disease
Liver enzyme elevation caused by, **6**:70

Pain
Chronic, as sign of battered woman syndrome, **11**:107
In musicians, as symptom of overuse, **11**:129
Quantitation of, trick for eliciting, **8**:68
Referral, physiology of, in woman's pelvis, **6**:13
See also specific anatomic sites

Palsy
Bell's
Lyme disease as cause of, **3**:64
As sign of complicated otitis media, **18**:18
See also *Movement disorders; Paralysis*

Pancreatitis
Acute, pleural effusion as sign of, **11**:96
Differentiated from perforated duodenal ulcer, **14**:143
Gallstone-related, cholecystectomy for, **2**:53

Pancuronium
For intubation in acute asthma, **7**:94

Pap smear
In the elderly, importance of, **16**:24

Papillitis
Diagnosis of, **17**:23

Papules
Pearly penile, diagnosis of, **12**:58

Paracentesis
Large-volume, for ascites, **18**:45

Paralysis
Acute muscular, diagnosis and treatment of, **4**:101
Diagnosis and treatment of, **19**:21
Facial, from trauma to ear or face, **18**:20
Intubation in cervical spine injury as cause of, **21**:68
Periodic, diagnosis of, **4**:104
As sign of stroke, **14**:112
Tick, differentiated from botulism, **2**:94
Todd's, nonketotic hyperglycemia as cause of, **21**:37
See also *Movement disorders; Palsy*

Paraquat
Poisoning, **3**:161

Paratonia
See *Gegenhalten*

Parents
Abusive, counseling of, **11**:115
Education of, concerning febrile seizures, **11**:197
Informing, after death of child, **6**:74

Paresthesias
In carpal tunnel syndrome, **3**:87
Stocking-glove, from nitrous oxide abuse, **3**:121

Parkinson's disease
Diagnosis and treatment of, **19**:21
Gait impairment as sign of, **8**:53

Partial thromboplastin time
In bleeding disorders, **8**:152

Patella
Injury
Assessment of, **3**:134
Pitfalls in diagnosing, **6**:111
See also *Knee*

Pelvic inflammatory disease
Vaginal bleeding caused by, **9**:86
Diagnosis and treatment of, **6**:28; **8**:33

Pelvis
Insufficiency fracture of, mimicking metastatic bone disease, **9**:77; **21**:173
Pain in woman's
Physiology, diagnosis, and treatment of, **6**:23

Penicillin
For acute joint pain from gonococcemia, **16**:83
For ehrlichiosis, **14**:102
For PID, efficacy of, **8**:37
Prophylactic
For endocarditis in dental procedures, **1**:82
After high-voltage electrical injury, **13**:94
In mouth wounds, **19**:89
In suspected Lyme disease, **10**:49
Resistance to, enterococcal, **16**:59
For syphilis, **3**:114

Penis
Pearly papules on, diagnosis of, **12**:58
Trick for releasing from zipper, **6**:96

Pentamidine
For Pneumocystis pneumonia, **2**:27; **9**:74

Pericardiocentesis
For penetrating chest trauma, **20**:85
Percutaneous, for cardiac tamponade, **8**:136

Pericarditis
Chest pain in young adults caused by, **2**:66
Diagnosis and treatment of, **8**:131, 136

Perihepatitis
Associated with PID, **6**:31

Peritonitis
Chemical, from perforated duodenal ulcer, **14**:143
Localized, in diagnosis of appendicitis in children, **12**:45
Spontaneous bacterial, as complication to ascites, **18**:45

Perlèche
Diagnosis of, **8**:105

Pesticide
Poisoning, **3**:152

Pharyngitis
Differentiated from measles, **17**:99
Emergent, **18**:32
As precipitant of chronic bronchitis, **8**:109
As sign of sinusitis, **21**:88

Phenobarbital
For pediatric febrile seizures, **11**:197

Phentolamine
For pheochromocytoma, **8**:98

Phenytoin
For theophylline overdose, **15**:86

Pheochromocytoma
Differentiated from anaphylaxis, **16**:56
Emergent hypertension caused by, **8**:98

Phosphate
Inefficacy of, for diabetic ketoacidosis, **8**:31

Photocoagulation
Laser, for diabetic retinopathy, **11**:87

Phycomycosis
As complication of orbital cellulitis, **9**:69

Physiotherapy
For chronic bronchitis, **20**:71
For COPD exacerbation, **7**:96
For foot and ankle injuries, **13**:20
For pneumonia, **7**:88

Phytophotodermatitis
Diagnosis and treatment of, **14**:108

Pilocarpine
For acute glaucoma, **9**:68

Plants
Field, toxicity from, signs and treatment of, **11**:58
Forest, toxicity from, signs and treatment of, **11**:61
Marsh, toxicity from, signs and treatment of, **11**:60
Poisonings related to, **11**:20
Vegetable, toxicity from, signs and treatment of, **11**:49

Plaques
Hollenhorst, of the retina, as signs of carotid artery disease, **20**:60

Plasmapheresis
For toxic epidermal necrolysis, **14**:72

Plethysmography
For DVT in lower extremities, **7**:48
Serial impedance, **13**:154
For suspected pulmonary embolism, **4**:93

Pneumonia
Anaerobic, diagnosis and treatment of, **1**:33
Antibiotic selection for, **7**:83
Atypical, diagnosis and treatment of, **14**:166, 171
Bronchitis differentiated from, **8**:109; **20**:68
In cardiac patients, **7**:33
Chlamydia psittaci as cause of, **14**:171
As complication of chronic bronchitis, **20**:71, 75
Coxiella burnetii as cause of, **14**:174
In diabetic patient, complications of, **4**:49
Diagnosis of, **7**:78
Francisella tularensis as cause of, **14**:174
Influenza-related, **17**:61, 63
Treatment of, **17**:70
After inhalation injury, **7**:60
Legionella, diagnosis and treatment of, **14**:168
Mycoplasma, diagnosis and treatment of, **14**:166
Pathogens in, **7**:79
Pneumocystis, diagnosis and treatment of, **2**:26; **9**:71
In quadriplegic, **14**:129
Risk factors for, **7**:77
Round, differentiated from lung cancer, **2**:54

Pneumonitis
Hypersensitivity, diagnosis and treatment of, **19**:63, 71

Pneumothorax
Dangers of rapid lung reexpansion in, **10**:80
Intubation-induced simulation of, **20**:131
Risk of, with nitrous oxide use, **3**:124
From scuba diving, **10**:64
Spontaneous, in Pneumocystis pneumonia, **9**:76
In stab wound to chest, **21**:81
Treatment of, without thoracostomy, **2**:45

Poisoning
Activated charcoal vs ipecac for, **14**:154
Agricultural, diagnosis and treatment of, **3**:151
Hotlines, **14**:196
See also specific agents

Poliomyelitis
Differentiated from botulism, **2**:94
Paralysis caused by, **19**:21
Weakness caused by, **4**:104, 109

Polyneuropathy
After high-voltage electrical injury, **13**:94

Potassium
Instability of, in diabetic ketoacidosis, **8**:31

Potassium hydroxide
In "sniff" test for diagnosis of vaginosis and vaginitis, **20**:121, 124

Pralidoxime
For organophosphate poisoning, **3**:158

Prednisone
For anaphylaxis prophylaxis before contrast studies, **16**:55
For cluster headache prophylaxis, **14**:164
For COPD, **17**:116
For myasthenia gravis, **4**:112

Pregnancy
Abnormal, as sign of disseminated intravascular coagulation, **8**:148
Battering during, incidence of, **11**:107
Chorea in, **19**:33
Complications of, as cause of vaginal bleeding, **9**:86
CO poisoning in, hyperbaric oxygen for, **12**:46
Diabetic ketoacidosis caused by, **8**:23
Ectopic
Pelvic pain caused by, **6**:24
PID associated with, **8**:33
Hepatitis testing during, **16**:126
High-altitude effects on, **5**:36
Influenza immunization in, **17**:86
Listeriosis during, risk of, **15**:31
Malaria during, dangers of, **13**:144
Ruling out, in suspected PID, **8**:33, 38
Toxoplasmosis in, dangers of, **17**:36
Vaginal irritation in, **20**:120

Pressure
Compartment, measurement of, in hand injuries, **14**:137
Intraocular
Lowering, for retinal artery occlusion, **20**:60
Measurement of
Before ophthalmoscopy, **17**:20
In orbital fracture, **13**:83
Local, to control bleeding scalp, **13**:71
Positive-end expiratory, in ARDS, **7**:67
Pulmonary, excessive, in scuba diving, **10**:64

Primidone
For essential tremor, **19**:30

Procainamide
For wide-complex tachycardia, **2**:51

Prochlorperazine
For glaucoma, **1**:115
For vascular and tension headache, **12**:51

Progesterone
For endometrial stability, **9**:92

Propranolol
For performance anxiety in musicians, **11**:129; **19**:29

Prothrombin time
Abnormal, in bleeding disorders, **8**:150
In assessment of anticoagulant dosage, **11**:176

Pseudoaneurysm
From blunt trauma, **13**:147
Iatrogenic, diagnosis and treatment of, **21**:69

Pseudoappendicitis
Chlamydial, differentiated from measles, **17**:99

Pseudogout
As cause of acute joint pain, **16**:83

Pseudohyponatremia
Hyperglycemia as cause of, **20**:23
Lab inaccuracy as cause of, **12**:87

Psittacosis
Diagnosis and treatment of, **14**:171

Psychiatric patients
Among the homeless, **4**:44
Interview of, procedure for, **14**:27

Psychosis
Toxic, from nitrous oxide abuse, **3**:121

Psyllium
For irritable bowel syndrome, **16**:72

Pulsus paradoxus
In diagnosis of cardiac tamponade, **8**:136

Purpura
Senile, diagnosis of, **12**:58

Pyelonephritis
Acute
Outpatient management of, **10**:83
Ruling out, in suspected PID, **8**:33
Misdiagnosis of, in appendicitis, **9**:40
Intravenous pyleography in, **5**:123

Pyloromyotomy
Frédet-Ramstedt, for pyloric stenosis in infants, **10**:44

Pylorus
Hypertrophic, palpation for, **10**:42

Pyrazinamide
For tuberculosis, **14**:101

Pyrimethamine
For cerebral toxoplasmosis in AIDS, **2**:28
With sulfadoxine, for malaria, possible resistance to, **13**:132

Quadriplegia
Pneumonia with, **14**:129

Quinacrine
For traveler's diarrhea, **12**:86

Quinidine
For malaria, available through CDC, **13**:141

Quinine
For malaria, **13**:140

continued

Quinolone
For gonorrhea, **11**:83

Radial head
Fracture, pitfalls in diagnosing, **5**:79
Subluxation, in children, **5**:85

Radiation
For gynecologic cancer in the elderly, **16**:27, 28

Ranitidine
For anaphylaxis prophylaxis before contrast studies, **16**:55
For perforated duodenal ulcer, **14**:149

Rapport
Establishing, in psychiatric interview, **14**:27

Rapture of the deep
See *Narcosis*

Rash
Diffuse macular, as sign of toxic shock syndrome, **8**:119
Facial, diagnosis of, **13**:111
Generalized, diagnosis of, **19**:35
On knees and elbows, diagnosis of, **16**:73
As late sign of measles, **17**:98
As sign of Lyme disease, **3**:58
As sign of varicella, **15**:49
Of wrists and arms, diagnosis of, **19**:35

Recompression
For treatment of CO poisoning, **12**:47
For treatment of dysbaric air embolism, **10**:66
See also *Oxygen, hyperbaric*

Reflex
Bulbocavernous, in spinal cord injury, **9**:29
Testing, trick for, **14**:195

Reflux
Gastrointestinal
Dysphagia caused by, **1**:54
Pediatric asthma caused by, **11**:120

Regurgitation
Aortic, in the elderly, auscultatory diagnosis of, **10**:23
Mitral, auscultatory diagnosis of, **10**:22
Pulmonic, in the elderly, auscultatory diagnosis of, **10**:23

Rehabilitation
From drug addiction, legal implications of certification of, **13**:95
After stroke, **14**:127

Renal failure
In cocaine-induced rhabdomyolysis, **6**:100
Hypertension as cause of, **8**:99
Oral hypoglycemics contraindicated in, **10**:80

Respiratory failure
Acute, diagnosis of ARDS in, **7**:67
In asthma and COPD, **7**:90
Chronic bronchitis as cause of, **20**:70
Danger of
In anaphylaxis, **16**:51
After stroke, **14**:115
In influenza, **17**:62
In pharyngitis, **18**:32

Resuscitation
Fluid
For diabetic ketoacidosis, **8**:24; **20**:24
For dysbaric air embolism, **10**:66, 75
For perforated duodenal ulcer, **14**:143
For pyloric stenosis, **10**:42, 46
For toxic epidermal necrolysis, **14**:72
For upper GI bleeding, **18**:78
After high-voltage electrical injury, **13**:93
Orders against, spelling out, **6**:53

Reticulocyte count
In assessment of macrocytic anemia, **14**:184

Retina
Disorders of, **11**:87; **16**:37; **17**:30
Hemorrhage of, at high altitudes, **5**:35
Interruption of blood supply to, emergent treatment of, **20**:57

Retinaculitis
Medial, causes and treatment of, **3**:136

Retinitis
CMV, screening for, in the immunocompromised, **16**:37

Retinoblastoma
Diagnosis of, **17**:30

Retinopathy
Diabetic, diagnosis and treatment of, **11**:87; **17**:30

Rhabdomyolysis
Acute, associated with cocaine abuse, **6**:100

Ribavirin
For influenza, **17**:69

Rickets
Associated with liver enzyme elevations, **6**:73
Diagnosis of, in a child, **7**:73

Rifampin
For tuberculosis, **14**:101
In homeless patients, **4**:27

Rimantadine
For influenza, **17**:64

Rosacea
Diagnosis and treatment of, **13**:112

S

Salmonella
Traveler's diarrhea caused by, **12**:80

Salpingitis
Diagnosis and treatment of, **6**:28
From untreated chlamydial infection, **16**:93
See also *Pelvic inflammatory disease*

Sarcoidosis
Pulmonary, diagnosis and treatment of, **19**:63

Scabies
In the homeless, **4**:22

Scalp
Nevus sebaceus of Jadassohn on, **5**:59
Routine examination of, in those at high-risk for melanoma, **16**:109
Wound
Rapid hemostasis for, **6**:99
Tricks for closure without suturing, **2**:103; **10**:31

Scanning
Bone
For ankle injury, **13**:18
For pelvic insufficiency fracture, **9**:77
CT
For back pain, efficacy of, **11**:164
For cerebral aneurysm or subarachnoid hemorrhage, **13**:105
For cerebral toxoplasmosis, in AIDS, **2**:28
For cervical spine injury, **9**:28
For duodenal ulcer, perforated, **14**:153
For ear trauma, **18**:20
For facial trauma, **18**:29
For gait impairment in the elderly, **8**:58
Inadvisability of, with nonsurgical lower back pain, **18**:66
For otitis
Malignant external, **5**:55
Media, **18**:19
For pelvic insufficiency fracture, **9**:77, 83
For Pneumocystis pneumonia, **9**:74
For sinusitis, **18**:29; **21**:93
For splenic injury, **1**:79
For stroke, **2**:109; **14**:114
For superior vena cava syndrome, **15**:69
Lung perfusion, for pulmonary embolism, **4**:90
Radionuclide
For back pain, **11**:164
Gallium 67
For interstitial lung disease, **19**:67
For myocarditis, **1**:89
Technetium 99m, after high-voltage electrical injury, **13**:94

continued

Brief Summary of Prescribing Information

AUGMENTIN™ amoxicillin/clavulanate potassium

Indications and Usage: AUGMENTIN® is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below.

Lower Respiratory Infections caused by β-lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.
Otitis Media caused by β-lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.
Sinusitis caused by β-lactamase-producing strains of *Hemophilus influenzae* and *Branhamella catarrhalis*.
Skin and Skin Structure Infections caused by β-lactamase-producing strains of *Staphylococcus aureus*, *E. coli*, and *Klebsiella* spp.
Urinary Tract Infections caused by β-lactamase-producing strains of *E. coli*, *Klebsiella* spp. and *Enterobacter* spp.

While AUGMENTIN is indicated only for the conditions listed above, infections caused by ampicillin susceptible organisms are also amenable to AUGMENTIN treatment due to its amoxicillin content. Therefore, mixed infections caused by ampicillin susceptible organisms and β-lactamase-producing organisms susceptible to AUGMENTIN should not require the addition of another antibiotic.

Bacteriological studies, to determine the causative organisms and their susceptibility to AUGMENTIN, should be performed together with any indicated surgical procedures.

Therapy may be instituted prior to obtaining the results from bacteriological and susceptibility studies to determine the causative organisms and their susceptibility to AUGMENTIN when there is reason to believe the infection may involve any of the β-lactamase-producing organisms listed above. Once the results are known, therapy should be adjusted, if appropriate.

Contraindications: A history of allergic reactions to any penicillin is a contraindication.

WARNINGS: SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTOID) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. ALTHOUGH ANAPHYLAXIS IS MORE FREQUENT FOLLOWING PARENTERAL THERAPY IT HAS OCCURRED IN PATIENTS ON ORAL PENICILLINS. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH ANY PENICILLIN, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS, AUGMENTIN SHOULD BE DISCONTINUED AND THE APPROPRIATE THERAPY INSTITUTED. **SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.**

Precautions: General: While AUGMENTIN possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is advisable during prolonged therapy.

A high percentage of patients with mononucleosis who receive ampicillin develop a skin rash. Thus, ampicillin class antibiotics should not be administered to patients with mononucleosis.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Drug Interactions: Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with AUGMENTIN may result in increased and prolonged blood levels of amoxicillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients. There are no data with AUGMENTIN and allopurinol administered concurrently.

AUGMENTIN should not be co-administered with Antabuse® (disulfiram).

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential.

Pregnancy (Category B): Reproduction studies have been performed in mice and rats at doses up to ten (10) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to AUGMENTIN. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Oral ampicillin class antibiotics are generally poorly absorbed during labor. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions and duration of contractions. However, it is not known whether the use of AUGMENTIN in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers: Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when AUGMENTIN is administered to a nursing woman.

Adverse Reactions: AUGMENTIN is generally well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug related side effects. The most frequently reported adverse effects were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%), and vaginitis (1%).

The overall incidence of side effects, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported reactions include: abdominal discomfort, flatulence and headache.

The following adverse reactions have been reported for ampicillin class antibiotics:

Gastrointestinal: Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black "hairy" tongue, enterocolitis and pseudomembranous colitis.

Hypersensitivity reactions: Skin rashes, urticaria, angioedema, serum sickness-like reactions (urticaria or skin rash accompanied by arthritis/arthralgia, myalgia, and frequently fever), erythema multiforme (rarely Stevens-Johnson Syndrome), and an occasional case of exfoliative dermatitis have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with oral penicillin (See Warnings).

Liver: A moderate rise in SGOT and/or SGPT has been noted in patients treated with ampicillin class antibiotics as well as with AUGMENTIN, but the significance of these findings is unknown. As with some other penicillins, and some cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Hemic and Lymphatic Systems: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1% of the patients treated with AUGMENTIN.

Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, behavioral changes, and/or dizziness have been reported rarely.

Dosage: Adults: The usual adult dose is one AUGMENTIN '250' tablet every eight hours. For more severe infections and infections of the respiratory tract, the dose should be one AUGMENTIN '500' tablet every eight hours.

Since both the AUGMENTIN '250' and '500' tablets contain the same amount of clavulanic acid (125 mg, as the potassium salt), two AUGMENTIN '250' tablets are not equivalent to one AUGMENTIN '500' tablet. Therefore, two AUGMENTIN '250' tablets should not be substituted for one AUGMENTIN '500' tablet for treatment of more severe infections.

Children: The usual dose is 20 mg/kg/day, based on amoxicillin component, in divided doses every eight hours. For otitis media, sinusitis and other more severe infections, the dose should be 40 mg/kg/day, based on the amoxicillin component, in divided doses every eight hours. Also available as AUGMENTIN '125' and '250' chewable tablets.

Children weighing 40 kg and more should be dosed according to the adult recommendations.

Beecham laboratories
Bristol, Tennessee 37620

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INDEX 1989

Thallium, for silent ischemia, **20**:100
Ventilation-perfusion, for pulmonary embolism, **7**:48; **13**:151

Scapula
Fracture, diagnosis and treatment of, **5**:67

Schizophrenia
Diagnosis of, in psychiatric interview, **14**:35

Sciatica
Test for, in gait disorders, **8**:58

Scintigraphy
Hepatobiliary, to identify acute cholecystitis, **11**:136
For splenic injury, **1**:79
Thallium, for unstable angina, **10**:59

Sclerosis
Amyotrophic lateral, as cause of paralysis, **19**:21
Tuberous, in a child, **7**:73

Sclerotherapy
Endoscopic, for esophageal variceal bleeding, **6**:37

Scorpion fish
Envenomation by, **12**:38

Scuba diving
See *Diving*

Sea
Anemones, envenomation by, **12**:28
Cucumbers, envenomation by, **12**:32
Urchins, envenomation by, **12**:32

Seat belts
Cervical trauma from uneven restraint by, **17**:46

Sedation
Indications for, of grieving parent, **6**:76
For suturing children, trick for, **12**:42

Seizures
Adult-onset, diagnosis and treatment of, **1**:20
Cocaine use associated with, **21**:26
Diabetes onset associated with, **21**:37
Dizziness caused by, **18**:74
In eclampsia, magnesium sulfate for, **8**:94
Febrile, diagnosis and treatment of, in children, **11**:186
Focal, surgery for, risks vs benefits of, **18**:58
In hypoglycemia, **20**:34
Preceding nonketotic hyperosmolar coma, **20**:31

Serum sickness
Differentiated from anaphylaxis, **16**:56

Sexual assault
In domestic violence, **11**:107

Sexually transmitted disease
HPV in men, diagnosis and treatment of, **13**:121
Screening and dual treatment for, **16**:93
Trichomoniasis coexistent with, **20**:121
Vaginitis differentiated from, **20**:120
See also specific diseases

Shigella
Traveler's diarrhea caused by, **12**:80

Shin splints
Anterior, **13**:20
Posterior, **13**:18

Shock
Decompression, from scuba diving, **10**:71
MAST suit for, inadvisability of, **20**:86
Precipitous, differentiated from toxic, **8**:122
See also *Electrical injury; Syndrome, toxic shock*

Shoulder
Injury
Pitfalls in diagnosing, **5**:64
In wind players, **11**:128
X-ray diagnosis of, **3**:183
Pain
As sign of metastatic cancer, **15**:27
X-ray diagnosis of, **13**:155

Shrubs
Ornamental, toxicity from, signs and treatment of, **11**:51

Sigmoidoscopy
For early detection of colon cancer, **16**:91

Sign
Anterior drawer, in knee injury, **3**:129, 134
Ballance's, in splenic injury, **1**:76
Chandelier, in pelvic peritoneal irritation, **6**:24
Kehr's, in splenic injury, **1**:76
"Lipstick," for cervical trauma, **17**:46
Murphy's, in obstructive cholecystitis, **11**:136
Nikolsky, in toxic epidermal necrolysis, **14**:70
Saegesser's, in splenic injury, **1**:76
String, in pyloric stenosis, **10**:44
Target, in ear trauma, **18**:20
Tinel's, in carpal tunnel syndrome, **3**:87

Silicosis
Diagnosis and treatment of, **19**:64

Silo-filler's disease
Nitrogen dioxide as cause of, **7**:62

Sinus
Ethmoidal, adenocarcinoma of, **4**:62
Infection, from influenza, **17**:72
Paranasal, barotraumatic effects on, **10**:63

Sinusitis
Acute, diagnosis and treatment of, **21**:87
Emergent or complicated, **18**:25, 33

Skin
Bends, in decompression sickness, **10**:71
Cancer
Diagnosis of, **17**:90
Dysplastic nevi as precursor to, **16**:104
Neck mass caused by, **4**:62

"Fish-scale," diagnosis of, **2**:41
Injury
In coelenterate envenomation, **12**:28
To hand, **14**:132
High-voltage electrical, **13**:93
Liquid detergent as cause of, **15**:53
Signs
In acute joint pain, **16**:82
In brown recluse spider envenomation, **14**:39
In interstitial lung disease, **19**:67
In syphilis, **3**:107
Sloughing of, in toxic epidermal necrolysis, **14**:68
See also specific conditions

Smoke
Inhalation injury from, **7**:53

Smoking
Associated with chronic bronchitis, **8**:112; **20**:70
As risk factor for head and neck cancer, **4**:62

Sodium
Restriction, for ascites, **18**:42
Serum, formulas for calculating accurately, **12**:90

Sodium thiosulfate
As antidote for cyanide poisoning, **9**:45

Spasm
Bronchial, trick for inhaler modification, **2**:103
See also *Vasospasm*

Spasticity
Of a limb, diagnosis of, **19**:22

Speech
Difficulties, as sign of stroke, **14**:112, 115
Distorted, as sign of pharyngeal injury, **18**:33
Signs, in psychiatric interview, **14**:32

Sphincterotomy
For bile duct stones, **11**:84

Spider
Brown recluse, envenomation from, **14**:39

Spinal cord
Injury, in decompression sickness, **10**:71

Spine
Cervical
Assessment and management of injury to, **9**:22
Controversy over oral intubation in injury to, **21**:63
"Lipstick sign" in injury to, **17**:46
Need for x-rays of, **17**:39
Normal variant of, in children, **1**:117
Trauma
X-ray diagnosis of, **19**:95
Vertical, from a fall, **14**:209

Spirometry
For chronic bronchitis, **20**:70
Interpretation of, **13**:35

Spironolactone
For ascites, **18**:42

Spleen
Injury to
Nonsurgical management of, **5**:100
Occult, in blunt trauma, **1**:73

Splint
For hand injuries, **3**:94
Sandwich, for burns, **12**:66
For position-dependent nerve compression in musicians, **11**:129
Short-leg posterior, trick for applying, **10**:31

Spondylitis
Ankylosing, diagnosis and treatment of, **19**:64

Spots
Cotton-wool, differentiated from retinitis, **16**:39
Cherry-red, on fundus, as sign of Tay-Sachs disease, **6**:103
Fordyce, differentiated from Koplik, **17**:104
Koplik, as sign of measles, **17**:103

Sprains
Ankle, **13**:29

Starfish
Envenomation by, **12**:36

Steam inhalation
For acute bronchitis, efficacy of, **8**:113

Stenosis
Aortic, in the elderly, auscultation of, **10**:22
Congenital hypertrophic pyloric, in infants, **10**:42
Mitral, in the elderly, auscultatory diagnosis of, **10**:25

Steroids
For acute asthma, **7**:28, 93
For alcoholic hepatitis, **20**:90
For bacterial meningitis, **8**:45
For bursitis, intrabursal, **8**:74
For chronic bronchitis, **20**:77
Contraindicated in ARDS, **7**:70
Contraindicated in conjunctivitis, **1**:102
For COPD, **7**:96
For gout or pseudogout, **16**:83
Inhalation of, trick for improving delivery during, **14**:195
For interstitial lung disease, **19**:70
Long-term risks of, **17**:114
For pericarditis, controversy over, **8**:136
As risk factor for Pneumocystis pneumonia, **9**:71
For spinal cord injury, controversy over, **9**:30
For temporal arteritis, **9**:69

Stimulation
Electrogalvanic, for ankle injury, **1**:70
Transcutaneous electrical nerve, for interstitial cystitis, **11**:156

Stingray
Envenomation by, **12**:37; **19**:11 (letter)

Stings
Hymenoptera, as cause of anaphylaxis, **16**:52
Marine animal, presentation and treatment of, **12**:26

Stomach
Herniated, x-ray appearance of, **18**:98

Streptokinase
For thromboembolic stroke, **2**:110

Streptomycin
For tuberculosis, **14**:101

Stress
Psychological, role in interstitial cystitis, **11**:151
Symptoms of, in battered women, **11**:107
See also *Tests*

Stroke
Dizziness caused by, **18**:74
Error in diagnosis of, **21**:167
Gait impairment from, in the elderly, **8**:52, 58
Hemorrhagic vs ischemic, **14**:112
Management of, **14**:120
Hypertension in, emergent treatment of, **8**:94
Lacunar, **14**:115
Rehabilitation after, **14**:127
Surgical vs medical treatment for, **2**:109

Stye
Diagnosis and treatment of, **1**:103

Suicide
Warning signs of, **4**:75
In psychiatric interview, **14**:29
Risk of, in battered women, **11**:106

Sunburn
As risk factor for melanoma, **16**:104, 109

Surgery
Bypass, indications for, in silent ischemia, **20**:106
For chest trauma, **20**:82
For gallstones, unnecessary, in asymptomatic diabetics, **14**:49
For gamekeeper's thumb, **13**:115
For gynecologic cancer in the elderly, **16**:27, 28, 33
Hypertension during, management of, **8**:100
For hypothenar hammer syndrome, **17**:121
For otitis media, **18**:18
For pediatric appendicitis, indications for, **12**:45
For perforated duodenal ulcer, **14**:153
For pulmonary embolism, criteria for, **7**:51
Pulmonary function testing before, **13**:35
"Second look," after initial surgery for ovarian cancer in the elderly, **16**:36
For seizures, risks vs benefits of, **18**:58
For spinal cord injury, controversy over, **9**:32
For spleen injury in adults, advisability of, **5**:100
For superior vena cava syndrome, **15**:74
Tests before, guidelines for, **11**:141
Toxic shock syndrome caused by, **8**:119, 122
For upper GI bleeding, **18**:84
See also specific procedures and conditions

continued

Suturing
Children, tricks for anesthesia before, **12**:42; **13**:78; **14**:195
Finger, trick for avoiding hematoma in, **4**:82
Scalp
Hair knots in place of, tricks for, **2**:103; **10**:31
To stop bleeding, **13**:75

Sympathectomy
Lumbar, for atheromatous embolism, **21**:76

Syncope
Differentiated from seizure, **1**:22
Lyme carditis as cause of, **14**:54
Ruling out arrhythmias as cause of, **14**:40
See also *Dizziness; Vertigo*

Syndrome
Acquired immune deficiency, see *AIDS*
Adult respiratory distress, see *ARDS*
Battered woman, intervention in, **11**:104
Blue toenail, **13**:30
Carcinoid, differentiated from anaphylaxis, **16**:56
Carpal tunnel
In hand injuries, **3**:87
In musicians, **11**:127
Compartment
In extremity injuries, **6**:124
In hand injuries, **14**:134
"Dung lung," in sewage workers, **7**:62
Guillain-Barré
Differentiated from botulism, **2**:94
Weakness caused by, **4**:103, 109
Heel spur, **13**:22
Hypothenar hammer, as cause of ischemic fingers, **17**:119
Irritable bowel, acute exacerbation of, **16**:67
Myasthenic, weakness caused by, **4**:103, 109
Nerve entrapment, in musicians, **11**:129
Os trigonum, **13**:22
Postconcussion, related to cervical trauma, **8**:7 (letter)
Ramsay Hunt, diagnosis and treatment of, **3**:76
Reiter's, as cause of acute joint pain, **16**:83
Restless leg, differentiated from myoclonus, **19**:32
Reye's
Danger of, in children taking aspirin, **17**:64
In pediatric febrile seizures, **11**:197
"Shaken baby," **16**:110
Staphylococcal scalded skin, differentiated from toxic epidermal necrolysis, **14**:70
Superior vena cava, diagnosis and treatment of, **15**:69
Tarsal tunnel, from sports injury, **13**:22
Thoracic outlet, in musicians, **11**:129
Toxic shock
Diagnosis and treatment of, **8**:119
Misdiagnosis of, medicolegal implications of, **18**:51
Urethral, compared to interstitial cystitis, **11**:150

Synovial fluid
Examination of, in acute joint pain, **16**:80

Synovitis
Chronic reactive, after ankle injury, **1**:71
In sea urchin envenomation, **12**:35

Syphilis
Diagnosis and treatment of, **3**:105
Early CNS involvement in, **10**:91
PID associated with, **8**:37
Retinitis from, differentiated from CMV retinitis, **16**:39

Systemic lupus erythematosus
Acute joint pain caused by, **16**:84
Coagulation disorders in, **8**:152

Tachycardia
In anaphylaxis, **16**:51
From dehydration, with perforated ulcer, **14**:143
As indication for rectal temperature measurement, **20**:116
Ventricular
Procainamide for, **2**:51
Verapamil contraindicated in, **1**:99
Wide QRS complex in, **9**:42

Tampons
Toxic shock syndrome associated with, **8**:126

Taping
Ankle injury, **13**:20
In cervical spine trauma, efficacy of, **9**:24
Dislocated finger, **3**:88
Gamekeeper's thumb, **13**:116
Ingrown toenail, trick for, **4**:82
Orotracheal tube, **14**:86
Toe
In fracture, trick for, **21**:111
In metatarsophalangeal dislocation, **6**:124

Tay-Sachs disease
Ophthalmologic diagnosis of, **6**:103

Teeth
Nursing caries as cause of decay of, in small child, **18**:67

Temporal bone
Fracture of, **18**:20

Tendinitis
Achilles, **13**:20
Calcific, of rectus femoris muscle, x-ray diagnosis of, **9**:97
Musculoskeletal angina caused by, **19**:48
Patellar, causes and treatment of, **3**:135
Peroneal, **13**:20

Tendon
Achilles
Evaluating injury to, **1**:66
Rupture of, from sports injury, **13**:32
Damage, in hand injuries, **14**:133
Peroneal subluxating, **13**:20
See also *Tendinitis*

Terbutaline
Subcutaneous, for acute asthma, **7**:93

Terfenadine
For anaphylaxis prophylaxis before contrast studies, **16**:55

Tests
Allen
For hypothenar hammer syndrome, **17**:120
For radial arterial punctures, **21**:72
Allergy, for childhood asthma, **11**:123
For ankle injury, **1**:65, 66, 68
Antibody
Antinuclear, for lupus erythematosus, **16**:84
IgG, for toxoplasmosis, **17**:36
Monoclonal, for trichomoniasis, **20**:124
Autoanalyzer, for meningitis, **21**:41
Of balance and gait, in the elderly, **8**:53
Chiron, for hepatitis screening, **16**:136
Chlamydial antigen, reliability of, **16**:93
Coagulation, for bleeding disorders, **8**:145
For cocaine intoxication, **21**:31, 34
Cold-agglutinin, for Mycoplasma pneumonia, **14**:168
For crystals in synovial fluid, in acute joint pain, **16**:80
Electrophysiologic, to rule out arrhythmia after syncope, **14**:40
For endotracheal tube placement, **17**:93
Exercise
Preoperative, indications for, **11**:148
In screening for silent ischemia, **20**:100
For unstable angina, **10**:59
Gag reflex, for hysteria, **10**:31
For gait disorders, **8**:58
Glucose
Fingerstick, for movement disorders, **21**:38
Reagent strip, for meningitis, **21**:41
For gonorrhea, in asymptomatic women, **13**:64
For hand injuries, **14**:134, 137
For hand innervation in upper extremity injury, **5**:70
Head-hanging, to evaluate the progress of sinusitis, **18**:25
For hepatitis, **10**:35; **16**:126, 135
For irritable bowel syndrome, **16**:70
For knee injuries, **3**:129
Laboratory, utility of, in
Anemia, **14**:180, 186, 191
Diabetic ketoacidosis, **8**:22
Suspected stroke, **14**:116
Unexplained fever, **5**:112
Liver function, abnormal in asymptomatic patient, **6**:69
For Lyme disease, **14**:56
Unreliability of, **13**:46
For malaria, **13**:137
Nylen-Barany, for dizzy patients, **18**:71
For ovarian cancer, development of, **16**:33
For pediatric appendicitis, utility of, **12**:45

Phalen's, for carpal tunnel syndrome, **3**:87
Pinhole, for diabetic retinopathy, **11**:89
Preoperative, **11**:141; **13**:35
Progesterone challenge, for endometrial cancer in the elderly, **16**:27
Pulmonary function, **13**:35
For interstitial lung disease, **19**:63
For toxic gas inhalation, **7**:60
Range-of-motion
For ankle injuries, **1**:65
For gait disorders, **8**:53, 58
For knee injuries, **3**:129
Rebound, for peritoneal irritation in abdomen, **6**:24
Red-glass, for weakened eye muscles, **4**:105
Reflex
For spinal cord injury, **9**:29
Trick for, **14**:195
Schilling, for pernicious anemia, **11**:102
Sensorimotor function, for spinal cord injuries, **9**:29
Serum sodium, lab inaccuracies in, **12**:87
"Sniff," for diagnosis of vaginosis and vaginitis, **20**:121, 124
Stress
For chest pain, **19**:46
Thallium, to measure cardiac effects of influenza, **17**:76
For thrombophilia, **6**:50
For thyroid function, **13**:61
Toluidine blue, for vulvar cancer in the elderly, **16**:28
Tuberculin
For asymptomatic tuberculosis, **21**:63
Determination of therapy after, **14**:97
Tuning fork
For ear trauma, **18**:20
For otitis media, **18**:18

Tetanus prophylaxis
After hand injuries, **14**:140
After high-voltage electrical injury, **13**:94

Tetracycline
For bronchitis prophylaxis, **8**:116
For ehrlichiosis, **14**:102
For malaria, **13**:141
For syphilis, **3**:115

Tetraglycine hydroperiodide
For prevention of traveler's diarrhea, **12**:85

Thalassemia
Anemia caused by, **14**:181

Thallium
Poisoning
Alopecia as sign of, **1**:40
Pediatric, **3**:161
See also *Scanning*

Theophylline
For acute asthma, **7**:25, 93
For chronic bronchitis, **20**:77
Overdose, diagnosis and treatment of, **15**:86

Thiamine
Deficiency, in the homeless, **4**:28

Thiazide
Risk of hyponatremia from, **11**:162

Thoracentesis
Improvising equipment for, **4**:82
For pleural effusion after abdominal trauma, **11**:93, 101

Thoracostomy tube
For pleural effusion, **11**:96

Throat
ENT emergencies involving, referral for, **18**:16

Thrombocytopenia
Causes of, **8**:146, 152, 157

Thrombolysis
In acute MI, importance of early transport for, **16**:123
For cocaine-induced MI, **21**:35
For pulmonary embolism, controversy over, **7**:51
As risk factor for atheromatous embolism, **21**:73
For superior vena cava syndrome, **15**:72
See also *Tissue plasminogen activator*

Thrombophilia
As cause of deep vein thrombosis, **6**:47
Diagnosis of, risk factors for, **6**:50

Thrombophlebitis
Diagnosis and treatment of, in a child, **3**:75

Thrombosis
Cavernous sinus, as complication to sinusitis, **18**:29; **21**:97
Cerebral, surgical vs medical management of, **2**:109
As complication of arterial puncture, **21**:69
Deep vein
In calf, anticoagulation for, **6**:59
Misdiagnosed as gout, **18**:94
Silent pulmonary embolism caused by, **13**:151
Thrombophilia as cause of, **6**:47
Treatment of, to avoid pulmonary embolism, **4**:88
Retinal occlusion caused by, **20**:60
Stroke caused by, **14**:112
See also *Embolism*

Thrush
In the immunocompromised, **15**:20

Thumb
Gamekeeper's, diagnosis and treatment of, **13**:115
Nail, deformity of, **15**:49

Thyroid
Cancer, misdiagnosed as goiter, **2**:91
Disorders, liver enzyme elevations caused by, **6**:73
Testing function of, **13**:61

Thyroiditis
Subacute, unexplained fever caused by, **5**:119

Thyrotoxicosis
Tests to confirm, **13**:62

Tibia
Fractured, assessment of, **6**:112

Ticks
Removal of, tricks for, **14**:122; **18**:41
See also *Bites; Paralysis;* specific diseases

Ticlopidine
For stroke prophylaxis, **14**:122

Tics
Diagnosis and treatment of, **19**:33
Habit, thumbnail deformity from, **15**:50

Tinea pedis
Diagnosis and treatment of, **10**:97

Tinnitus
As sign of serious ear trauma, **18**:19

Tissue plasminogen activator
For ischemic stroke, **14**:114
For thromboembolic stroke, **2**:110

Tobramycin
For endocarditis, **8**:42

Toe
Fractured, trick for buddy taping, **21**:111
Purple, atheromatous embolism as cause of, **21**:74
Turf, **13**:30

Toenail
Ingrown, trick for treating nonsurgically, **4**:82
Hematoma beneath, **13**:30

Tonometry
Schiotz, to check for ocular injury with orbital fracture, **13**:83

Tophi
In hands, **1**:57
As sign of gout, **16**:82

Torsion
Ovarian, pelvic pain caused by, **6**:33

Toxic epidermal necrolysis
Diagnosis and treatment of, **14**:68

Toxicology
Self test, for ABMT exam, **15**:77
See also *Poisoning;* specific toxins

Toxoplasmosis
Differentiation from mononucleosis, **17**:36
Encephalitic, in AIDS, **2**:27
Retinal, differentiated from CMV retinitis, **16**:39

Tracheotomy
In neck trauma, **18**:36

Traction
Axial, for oral intubation, dangers of, **21**:168
continued

Transcutaneous electrical nerve stimulation
For interstitial cystitis, **11**:156

Transfer
Of critically ill patients, medicolegal issues surrounding, **2**:71
Of patients with acute MI, benefits of, **16**:119

Transfusion
See *Blood*

Transient ischemic attacks
Dizziness caused by, **18**:74
Syncope caused by, **14**:40

Transillumination
Procedure for, in sinusitis, **21**:88

Transplantation
Liver, due to fulminant hepatitis, **16**:136

Trauma
Acute joint pain caused by, **16**:85
Blunt, myocardial contusion caused by, **5**:47
Electrical injury associated with, **13**:93
Facial, assessment and management of, **18**:29, 33
In the homeless, difficulties in treating, **4**:38
Pseudoaneurysm after, **13**:147
Repeated, as cause of ischemic fingers, **17**:119
Vertical, from a fall, **14**:209
See also *Barotrauma*; specific sites

Travel
Diarrhea from, diagnosis and treatment of, **12**:77; **18**:9 (letter)
Influenza immunization for, **17**:86
Malaria from, **13**:130
Prophylaxis during, **13**:141

Trees
Toxicity from, signs and treatment of, **11**:51

Tremor
Diagnosis and treatment of, **19**:23
As early sign of parkinsonism, **19**:24
As sign of stroke, **21**:167

Trench foot
In the homeless, **4**:43

Triage
In the ED, medicolegal implications of, **16**:40

Trichomoniasis
Diagnosis and treatment of, **20**:121

Trimethoprim-dapsone
For Pneumocystis pneumonia, **9**:75

Trimethoprim-sulfamethoxazole
For acute bronchitis, **8**:116
For Pneumocystis pneumonia, **2**:27; **9**:74

Trimetrexate
For Pneumocystis pneumonia, **9**:75

Trismus
Ventilation during, trick for, **18**:41

Tuberculosis
In AIDS, **2**:35
Extrapulmonary, **14**:101
Asymptomatic, utility of x-rays for, **21**:63
In the homeless, **4**:24
Miliary, unexplained fever caused by, **5**:113
Shorter therapy for, with negative sputum smears, **14**:97

Tularemia
Diagnosis and treatment of, **14**:174

Tumor
Carotid body, neck mass caused by, **4**:68
Cephalic, gait impairment as sign of, **8**:53
Liver enzyme elevations caused by, **6**:73
Lymphatic, as cause of superior vena cava syndrome, **15**:69
Of ocular fundus, diagnosis of, **17**:30
Pott's puffy, sinusitis as cause of, **21**:88, 100
Sternocleidomastoid, diagnosis of, in infant, **8**:105
Strokelike symptoms caused by, **14**:116
Unexplained fever caused by, **5**:114

Tympanic membrane
Rupture of, from nitrous oxide abuse, **3**:124
See also *Hemotympanum*

Ulcer
Corneal, diagnosis and treatment of, **1**:106; **9**:67
Diabetic foot, cleaning maggots from, **18**:41
Duodenal, perforated, diagnosis and treatment of, **14**:143
Hunner's, see *Cystitis*
Peptic
Bleeding, as source of nosebleed, **17**:35
Gastric outlet obstruction caused by, **10**:45
Venous stasis, in homeless patients, **4**:32

Ultrasonography
For DVT, **6**:60; **13**:154
For ectopic pregnancy, **6**:25
For endocarditis, **12**:61
Of liver, periodic, for hepatitis B carriers, **16**:131
For ovarian cancer in the elderly, **16**:33
For ovarian torsion, **6**:33
Vs peritoneal lavage for detecting abdominal injury, **15**:45
For PID, **8**:38
For pregnancy-related vaginal bleeding, **9**:87
For pyelonephritis, **5**:124
For sinusitis, **21**:93
For splenic injury, **1**:79
For suspected stroke, **14**:119
For symptomatic gallstones, **11**:136

Ureter
Injury to, assessment and treatment of, **3**:147

Urinalysis
Preoperative, indications for, **11**:148

Urinary retention
Misdiagnosis of, **13**:118

Urine dipsticks
For diagnosis of movement disorders, **21**:38
Reliability of, for detecting infection, **19**:41

Ursodiol
For gallstone dissolution, **11**:136

Urticaria
As sign of anaphylaxis, **16**:51

Vaginitis
Diagnosis and treatment of, **20**:118
Recurrent or recalcitrant, treatment of, **20**:130

Vaginosis
Bacterial, diagnosis and treatment of, **20**:120

Valsalva maneuvers
For middle-ear squeeze in scuba diving, **10**:62

Vancomycin
For endocarditis
In drug abusers, **8**:42
Prophylaxis during dental procedures, **1**:82
For penicillin-resistant enterococci, **16**:59

Varicella
In adolescents, **15**:49
Life-threatening complications of, **7**:63

Vascular disease
Collagen, unexplained fever caused by, **5**:114
Peripheral, in the homeless, **4**:31
Vertigo caused by, **16**:113
See also *Heart; Occlusion*

Vasospasm
Angina caused by, **2**:65
As cause of coronary ischemia, **15**:60

Vasovagal reactions
Differentiated from anaphylaxis, **16**:56

Vena cava
Obstruction of, **15**:69
Superior
Syndrome, **15**:69
Tube misplaced in, **2**:119
Umbrella in, for embolism prophylaxis in DVT, **6**:60

Venipuncture
Venodilation before, trick for, **6**:96

Venography
For DVT, **6**:60; **18**:94
For superior vena cava syndrome, **15**:69

continued

Ventilation
Mechanical
For acute respiratory acidosis in COPD, **7**:96
For pneumonia, **7**:85
Transtracheal, in cervical spine injury, **21**:68
During trismus, trick for, **18**:41

Ventilatory defects
Restrictive, causes of and testing for, **13**:41

Ventricular septal defect
In the elderly, auscultatory diagnosis of, **10**:25

Verapamil
For cluster headache prophylaxis, **14**:164
For cocaine-induced MI, **21**:35
Contraindicated in ventricular tachycardia, **1**:99
Dangers of, in ventricular arrhythmia, **9**:42
For unstable angina, **3**:45

Vertigo
Alternobaric, in scuba diving, **10**:64
Benign positional, **16**:116
Diagnosis of, simple approach to, **18**:71
Differentiating ischemic from inner ear, **16**:113

Vestibular disorder
Benign peripheral, as cause of dizziness, **18**:71

Vibration
As cause of anaphylaxis, **16**:55

Violence
Domestic, victims of, recognition of and aid to, **11**:104

Vision loss
Sudden, diagnosis and treatment of, **9**:69; **20**:59
Gait impairment caused by, in the elderly, **8**:52

Vitamin deficiency
B_{12}
Anemia caused by, **11**:102; **14**:179
In the homeless, **4**:28
From nitrous oxide use, **3**:118
D, elevated liver enzymes caused by, **6**:73
Drug-induced, in the elderly, **4**:56
K, causes and diagnosis of, **8**:146, 150
Supplements for, in perforated duodenal ulcer, **14**:150
See also *Thiamine; Niacin*

Vitiligo
Diagnosis and treatment of, **16**:74

Vitreous
Ocular, disorders of, **17**:23; **20**:66

Vomiting
With dizziness, diagnosis of, **18**:71
Nonbilious projectile, as sign of pyloric stenosis, **10**:42
As sign of hemorrhagic stroke, **14**:114

Von Willebrand's disease
Diagnosis of, **8**:157

Vulva
Cancer of, in the elderly, **16**:27

Vulvovaginitis
Candida, diagnosis and treatment of, **20**:127

Warfarin
For DVT, **4**:89
For ischemic stroke, **14**:121
For pulmonary embolism, **7**:50
Reduced-dose, advisability of, **11**:173
For stroke prophylaxis, **14**:122
For thrombophilia, **6**:50

Warts
Genital, as sign of HPV infection, **13**:125
See also *Condylomata*

Weakness
Acute, differential diagnosis and treatment of, **4**:101
As sign of overuse syndrome in musicians, **11**:128

Weight loss
In infant, as sign of pyloric stenosis, **10**:42
Mycobacterium avium intracellulare as cause of, in AIDS, **2**:35
Unexplained
With lower back pain, as sign of cancer, **18**:64
Undiagnosed diabetes as cause of, **20**:81

Weil's disease
Differentiated from toxic shock syndrome, **8**:122

Women
Domestic abuse of, recognition of and intervention in, **11**:104; **19**:11 (letter)

Wood's light
For finding antifreeze in injured eye, **8**:68

Wounds
Entrance and exit, in electrical injury, **13**:86, 93
Impalement, avoidance of MAST suit in, **20**:88
Irrigating, tricks for, **2**:103; **6**:96
Maggot infestation of
For debridement, **21**:111
For possibly improved healing, **13**:78; **18**:41
Puncture
In the foot, **6**:57
Likelihood of infection of, **21**:81
Pseudoaneurysm caused by, **21**:69
Stab, to chest, management of, **21**:171
Surgical, toxic shock syndrome caused by, **8**:119, 122
Trick for anesthetization of children's, **21**:111
See also *Trauma* and specific sites

Wrist
Block, procedure for, **13**:107
Fracture, assessment and treatment of, **5**:87
Rash on, **19**:35

XYZ

X-rays
For ankle injury, importance of, **1**:68
Calcific tendinitis shown on, **9**:97
Chest
For acute bronchitis, **8**:110
To check feeding tube placement, **6**:132
To check nasotracheal tube placement, **16**:137
Heart failure revealed by, **17**:124
For infection without fever in the elderly, **18**:91
For influenza, **17**:64
For penetrating trauma, importance of, **20**:82
For Pneumocystis pneumonia, **9**:72
Preoperative, indications for, **11**:142
Round pneumonia lesions on, **2**:54
For stab wounds, **21**:171
Utility of, in asymptomatic tuberculosis, **21**:68
For complicated pharyngitis, **18**:32
Effective verbal descriptions of, **5**:87
Elbow, pitfalls in interpreting, **5**:79
Esophageal, in diagnosis of foreign body, **21**:45
Hand
For gamekeeper's thumb, **13**:117
After trauma, **3**:80; **14**:137
Interstitial lung disease seen on, **19**:64
For lower back pain, to rule out cancer, **18**:63
For lower extremity trauma, pitfalls in interpreting, **6**:110
Pelvic, for insufficiency stress fracture, **21**:173
For perforated duodenal ulcer, **14**:144, 150
Pharyngeal, in search of chicken bone, **15**:97
Shoulder
In diagnosis of os acromiale, **3**:184
For dislocations, interpretation of, **5**:73
For unexplained pain, **13**:155
Sinus
For sinusitis, **18**:25
Interpretation of, **21**:89
Spinal
Cervical
Apparent abnormality in child's, **1**:117
For assessment of trauma, **9**:26; **17**:39
Role in diagnosis of back pain, **11**:164; **18**:63
For sports injuries to foot and ankle, **13**:18
In testing pulmonary function, **13**:44
For tibial stress fracture in child, **14**:213
For upper extremity injuries, pitfalls in reading, **5**:64

Zidovudine
For Pneumocystis pneumonia in AIDS, **2**:27

Zinc
Deficiency, in the homeless, **4**:28
Poisoning, diagnosis and treatment of, **8**:88

INDEX OF AUTHORS

AB

Abbott JT
Pelvic pain, **6**:23
Vaginal bleeding, **9**:85

Abdulla AM 8:92

Abelmann WH 1:89

Abram SR 11:164

Adams HP 14:112; **16**:9 (apology to)

Adinolfi MF 3:147

Aghababian RV 16:123

Akhtar M 9:42

Alarcón FJ 6:100

Albertson TE 14:154

Ali ZS 8:68

Amerson SM 21:41

Amlinger PR 11:9 (letter)

Anderson RL 10:37

Anwar R 11:104

Araujo OE 14:68

Arena JM 11:20

Armstrong D 15:23

Armstrong PW 10:59

Aronson MD
Gonorrheal testing, **13**:66
Unsuspected chlamydia, **16**:93

Aronson SG
Tricks of the Trade, **10**:31; **21**:111

Arts HA 13:83

Atkins HA
20 years of EM, **3**:3
The job, **21**:3

Auerbach PS 12:26; **19**:11 (reply to letter)

Bacchus H 20:20

Bade PG 20:82

Bader TF 18:42

Baeke JL 10:31

Baker CC 19:73

Baker JL 3:173

Baker-Zander SA 10:91

Ball SP 16:123

Baloh RW 16:113

Baltch AL 1:82

Banner W Jr. 15:77

Barbour AG 13:46

Barie PS 9:39

Barnett HJM 2:109

Batteiger BE 16:94

Bayer AS 3:49

Bayless P 17:39

Becker DM 6:59

Beller GA 20:100

Ben-Zvi JS 11:84

Bernat JL 1:20

Bewick DJ 17:75

Bickell W 20:86

Bitterman RA 18:9 (reply to letter)
Acute Abdomen
Nonspecific abdominal pain, **6**:63
Pelvic inflammatory disease, **8**:33
Gastric outlet obstruction, **10**:42
Acute traveler's diarrhea, **12**:77
Perforated duodenal ulcer, **14**:143
Upper gastrointestinal hemorrhage, **18**:77
Ingestion of foreign bodies, **21**:45

Bivins B 2:45

Black D 10:83

Blackwell J 21:74

Blatchly SW 12:9

Block EF 5:47

Bloom JN 16:37

Bloom T 10:31

Bonow JH 20:104

Boothman RC
Legal Rounds
Transferring critically ill patients under COBRA, **2**:71
Restraint in the ED, **8**:162
Switching counsel in midstream, **10**:55
Certifying that someone is drug free, **13**:95
Responsibilities of physicians on hospital committees, **14**:74
Triage responsibility, **16**:40
Does the diagnosis match the chart? **18**:51
Timeliness of physician action, **20**:35
Safety of presuit casual conversations, **21**:105

Bourgoignie JJ 6:100

Bowen V 14:131

Bowerman CR
Legal Rounds
Transferring critically ill patients under COBRA, **2**:71
Certifying that someone is drug free, **13**:95
Triage responsibility, **16**:40
Does the diagnosis match the chart? **18**:51
Timeliness of physician action, **20**:35

Brent CR 17:46

Brett AS 14:49

Brewer T 2:103

Brickner PW 4:21

Brien WW 21:81

Brody G 21:26

Broome CV 15:31

Brusch JL 5:108

Buchan A 2:109

Buckman RF Jr.
The injured spleen, **5**:100
Chest stab wounds, **21**:171

Burch J 20:86

Burke DS 3:176

Burrows B 20:68

Bush LM 16:59

C

Caceres J 9:42

Calmon J 16:59

Calubrian OV 14:166

Camporesi EM 12:46

Caravati EM 9:45

Carithers RL Jr. 20:92

Carmel R 11:102

Carroll SA 5:47

continued

AUTHOR INDEX

Carter VS 21:81

Chalfin L
Tricks of the Trade: **2**:103; **4**:82; **6**:96; **8**:68; **10**:31; **12**:42; **13**:78; **14**:195; **16**:86; **18**:41; **20**:57; **21**:111

Chambers HF 8:42

Chang JC 21:55

Chase RC 10:33

Checcio LM 2:103

Chelmowski MK 11:77

Chen D 21:74

Cherian J 21:74

Cherney CL 16:59

Chirgwin K 2:25

Chisholm RJ 10:59

Chisnall B 20:57

Chiu CY 3:49

Choi SC 10:37

Chrane DF 8:45

Chung MK 13:78

Ciesla ML 19:41

Clark DE 6:99

Clements ML 17:61

Click RL 2:60

Cohen PF 20:97

Cole HP III 20:59

Collier AC 10:91

Combes B 20:92

Come PC 1:89

Conces DJ Jr.
Misplaced Tube: **2**:119; **6**:131; **8**:175; **10**:113; **12**:101; **16**:137; **18**:97; **20**:131

Cooper KL 9:77

Cooperman A 11:84

Corder CN 21:74

Corrao JM 16:123

Cortelyou M 6:96

Cortes JR 10:31

Costello CM 10:49

Counselman F
Acute abdomen in the elderly, **3**:23
When fevers lead to seizures, **11**:186
Acute sinusitis, **21**:87

Critchlow CW 10:91

Crumpacker CS 1:89

Cunha BA
Lyme disease, **3**:55
Case Studies in Infectious Disease
Botulism, **2**:94
Toxic shock syndrome, **8**:119
Epidemic measles, **17**:97

Cusack JF 14:27

Cykiert RC 1:100; **16**:9 (reply to letter)

Czaja AJ 10:33

Dalen JE
Are you overdoing anticoagulant therapy? **11**:173
Transporting patients with acute MI, **16**:123

Dammin TC 4:82

D'Andrea G 14:122

Dawson JE 14:102

deGuise P 11:74

de los Santos E 13:61

Derlet RW 14:154

Deykin D 11:173

Deyo RA 18:63

Diehl AK 18:63

Diehl AM 20:92

DiMagno EP 2:53

Dire DJ
Let button batteries pass, **17**:42
Hyperglycemic movement disorders, **21**:37

Dolan PA 14:68

Doll DD 8:84

Donner MW 1:51

Doubleday WA 6:77

Dougherty J 12:51

Dowd DC 1:40

Dowling JB 5:95

Doyle MQ 12:42

Dubberly DD 4:82

Düber C 15:45

Duckert LG 13:83

Dufour DR 14:159

Dunham CM 5:100

Dutra C 18:41

Early CK 13:78

Eaton TL 8:68

Eisele DW 13:83

Elenbaas RM 19:89

Ellefson ME 17:55

Ellsworth AJ 5:41

Elms JJ 11:9 (reply to letter)

Embury SP 16:86

Epstein SE 20:104

Evans TC 5:63

Fallon HJ 20:92

Farfel Z 11:162

Farmer RG 19:54

Feder HM Jr. 10:49

Fein AM
Respiratory medicine today, **7**:2
Toxic gas inhalation, **7**:53, **12**:9 (reply to letter)
Cardiopulmonary Problems in the Office
Community-acquired pulmonary empyema, **1**:33
Cardiac patients with pneumonia, **7**:33
Pneumocystis carinii pneumonia, **9**:71
Pulmonary function testing, **13**:35
Atypical pneumonia, **14**:166
Superior vena cava syndrome, **15**:69
Interstitial lung disease, **19**:63
Cardiovascular effects of cocaine, **21**:26

Feinsilver SH 7:90

Feliciano D 20:86

Fernandez JA 6:100

Field D 6:16 (letter)
Tricks of the Trade: **4**:82; **14**:195

Finch D 17:11

Fishbein DB 14:102

Flanagan KM 1:9 (letter)

Flanigan T 17:114

Flint LJ 20:85

Flitcraft A 11:104

Flowers FP 14:68

Foulke GE 14:154

Fraiz J 16:94

Frame SB
Trauma Rounds
Isolated blunt splenic trauma, **1**:73
Biliary tract injuries, **5**:95
Pleural effusion after blunt penetrating trauma, **11**:93
Traumatic pseudoaneurysm, **13**:147
Brown recluse spider envenomation, **14**:39
Lipstick sign, **17**:46
Iatrogenic pseudoaneurysm of the radial artery, **21**:69

Frankel R 13:18

Freeman MR 10:59

Freidman LS 14:42

Freij BJ 8:45

Friedland GH 3:178
Friedman E 11:162

GH

Gabai IJ 14:164
Gaddis GM 8:68
Gage DG 4:22
Garcia T 18:41
Garvin KL 6:57
Gates P 2:109
Gellin BG 15:31
Gelman J 21:171
Gerard WA 14:195
Gersh BJ 14:42
Gilley LD 20:57
Ginzton L 3:49
Glatt AE 2:25
Gluck M 11:200
Goff JS 6:37
Goldberg RJ 16:123
Goldberg SK 13:35
Goodrich T 16:9
Gore JM 16:119
Gottridge J 21:63
Graboys TB 20:106
Grad A 16:113
Graham JA 6:96
Gray LM 18:41
Green RW 4:22
Greenson JK 20:50
Gregg K 13:78
Grosh J 21:171
Grossman J 12:9
Groth ML 7:23
Grüessner R 15:45
Grysen BE 12:9
Gude JK 8:109
Guerra J 14:159
Gupta T 16:91
Guterman JJ 20:47
Haas RG 17:55
Hackett PH 5:20
Hage ML 12:46
Halkin H 11:162
Halsey JH Jr. 14:114
Hammer MC 1:82
Hammill SC 14:42
Handsfield HH 10:91
Hanff PA 16:93
Hardin JG 16:80
Harris BH 6:2 (editorial)
Hauge MD 9:77
Hecker JH 5:63
Hedges JR 8:7 (letter)
Heller P 16:86
Henderson DK 3:170
Henry GL
Consent for treatment, **2**:9; **7**:11 (replies to letters)
Frivolous suits, **17**:11 (reply to letter)
Legal Rounds
Transferring critically ill patients under COBRA, **2**:71
Information release, **6**:125
Restraint in the ED, **8**:162
Switching counsel in midstream, **10**:55
Certifying that someone is drug free, **13**:95
Responsibilities of physicians on hospital committees, **14**:75
Triage responsibility, **16**:40
Does the diagnosis match the chart? **18**:51
Timeliness of physician action, **20**:35
Presuit casual conversations, **21**:105
Herbert V 11:103
Herlong HF 20:92
Herr RD 18:71
Hershey CO 2:54
Herzig WF 16:86
Hirsch BH 12:9
Hirsch J 11:173
Hirshberg PB 20:82
Hoffman JR 20:47
Holmes MD 16:93
Holubets MC 17:55
Hood C 13:78
Hook EW III 10:91
Horacek BM 17:75
Horowitz L 20:57
Hough C 8:51
Houston CS 5:20
Hoyte MJ 8:45
Huizinga WKJ 20:82
Hurewitz AN 7:23

IJK

Idell S 7:67
Ivnik RJ 18:58
Jacobson SJ
Avoidable Errors in Emergency Practice: **1**:99; **2**:99; **3**:97; **4**:49; **5**:45; **6**:34; **7**:63; **8**:129; **9**:51; **10**:80; **11**:67; **12**:99; **13**:118; **14**:129; **15**:27; **16**:110; **17**:35; **18**:94; **20**:81; **21**:167
Jagminas LJ 16:9
Jain U 14:195
Jarolim DR 21:74
Jazayeri M 9:42
Jazewski R 16:91
Jeffries M 8:68
Jehle D 17:36
Jenney DB 11:9 (letter)
Jennings WC 21:73
John JF Jr. 2:92
Johnson CC 16:59
Joly P 11:74
Jones B 1:51
Jones J 12:51
Jones RB 16:94
Jones WG 9:39
Joseph R 14:122
Judson FN 11:81
Jump LE 2:103
Juneau M 11:74
Jupiter JG 3:79
Kagan-Halley KS 1:40
Kahl PA 3:178
Kahn D 11:84
Kaliner MA 16:51
Kammer LM 8:51
Kane JJ 12:42
Kanel KT 5:123
Kannel WB 20:97
Kaplan MM 6:69
Kapoor W 14:40
Kapusnick RA 5:47
Katz BP 16:94
Katzman M 17:114
Keats TE
The Emergency X-ray: **1**:117; **3**:183; **5**:125; **7**:99; **9**:97; **11**:203; **13**:155; **14**:213; **15**:97; **17**:123; **19**:95; **21**:173

continued

AUTHOR INDEX

Keelan MH Jr. **11**:77
Kelen GD **3**:173
Keller E **18**:91
Kelley PW **14**:102
Kennard BD **8**:45
Kerr R **12**:42
Kerr TM **21**:171
Kilbourne ED
Influenza—the deadly effects, **17**:61
Now is the time to vaccinate, **17**:84
Kizer KW **10**:60
Klein NC **14**:166
Klein RS **3**:178
Klein-Schwartz W **1**:85
Knight V **17**:69
Kohn DW **18**:76
Kohn SR **18**:67
Kornreich F **17**:75
Kravitz M **12**:66
Krebs H-B **13**:121
Krenzelok EP **15**:53
Kresovich-Wendler K **20**:116
Kroboth FJ **5**:123
Krushell RJ **3**:79
Kuhns DL **17**:42
Kunkel SP
Thallium poisoning, **1**:40
The Toxic Emergency
Nitrous oxide, **3**:117
Kutner MH **21**:41

LMN

La Puma J **6**:53
Lacombe DC **7**:11
LaGrenade A **14**:159
Lam K **3**:49
Lambert B **20**:47
Lamy PP **4**:50
Lanczy TA **18**:41
Landesman SH **2**:25
Larson EB **5**:41
Latour J-G **11**:74
Laws EJ Jr. **18**:58
Lebel MH **8**:45
Lecky JW **5**:123
Lederman MM **17**:114
Lee S **18**:91
Lemon SM **10**:33
Lemos MJ **6**:99
Lennox JL **3**:176
Lerner AM **17**:75
Lesser ML **3**:178
Lesser RS **21**:63
Levine JR **3**:105
Levine M **11**:173
Levine PR **19**:45
Levinstein M **18**:91
Levison ME **16**:59
Levitt MA
A solution to wide-complex tachycardia, **2**:51
Indications for rectal temperature, **20**:113
Levy DE **14**:114
Lévy G **11**:74
Lim AS **16**:86
Lindenbaum GA **5**:47
Lipton FR **4**:44
Litin SC **9**:77
Litovitz TL
Treating boric acid ingestion, **1**:85
Artificial nail-remover toxicity, **9**:45
Litt JZ
Diagnosis at a Glance: **2**:41; **5**:59; **9**:36; **10**:97; **11**:167; **12**:57; **13**:111; **14**:107; **15**:49; **16**:73; **17**:89; **19**:35; **20**:107
Little NE **8**:7 (reply to letter)
In case of a broken neck, **9**:22
Lobel HO **13**:129
Lockwood AH **11**:125
Low R **2**:8 (letter)
Ludwig J **10**:33
Luk GD **16**:91
Lukeheart SA **10**:91
Maddrey WC
Viral hepatitis today, **16**:124
Corticosteroids for alcoholic hepatitis, **20**:90
Magnarelli LA **14**:102
Malaney KE **14**:27
Manktelow RT **14**:131
Manolis AS **11**:71
Marini D **10**:31
Marrie TJ **17**:75
Martin EC **11**:135
Marton KL **14**:49
Mascette AM **19**:45
Mason JD **14**:156
Massimilian JT **2**:103
Mathews JJ **18**:71
Mattox KL **20**:86
May DR **20**:59
Mayers MM **3**:178
Mazzaferri EL **13**:61
McAdam JM **4**:24
McAfee JH **8**:71
McCans J **11**:74
McCracken GH **8**:45
McCue F **13**:115
McCue JD **20**:118
McHenry MP **8**:51
McHugh MT **11**:113
McLaughlin DI **12**:42
McLeer SV **11**:104
McSwain NE Jr.
In sudden darkness, **20**:59
Emergency Procedures
Esophageal foreign body removal, **2**:85
Nasal hemorrhage, **5**:120
Bier block, **12**:73; **19**:11 (reply to letter)
Wrist block, **13**:107
Trauma Rounds
Isolated blunt splenic trauma, **1**:73
Ureteral injury, **3**:147
Biliary tract injuries, **5**:95
Pleural effusion after blunt penetrating trauma, **11**:93
Traumatic pseudoaneurysm, **13**:147
Brown recluse spider envenomation, **14**:39
Lipstick sign, **17**:46
Iatrogenic pseudoaneurysm of the radial artery, **21**:69
Meisler K **13**:18
Melita H **11**:72
Menkes JS
Upper extremity trauma, **5**:64
Lower extremity trauma, **6**:108
Mentges B **15**:45
Metzger C
Legal Rounds
Transferring critically ill patients under COBRA, **2**:71
Certifying that someone is drug free, **13**:95
Triage responsibility, **16**:40
Does the diagnosis match the chart? **18**:51
Timeliness of physician action, **20**:35
Presuit casual conversations, **21**:105
Meyer R **21**:63
Michelsen P **1**:82
Mickal E **4**:82
Miklozek CA **1**:89
Milgraum SS **16**:104
Militello PR **5**:100
Miller RT **8**:42

continued

AUTHOR INDEX

Minguillon MC 14:154
Mitchell MC 20:50
Mitchum D 12:45
Moire L 8:7 (letter)
Mollet DL 12:45
Montague TJ 17:75
Moon RE 12:46
Moreau JA 2:53
Morgan DP 3:151
Morres CA 21:37
Morris JA 6:82
Moser KM 4:87
Mueller DH 2:103
Mulcare RJ 4:31
Mullin GE 20:50
Narayan RK 10:37
Negus RA 21:41
Nelson JC 18:41
Newhall WJ 16:94
Newman MD 8:42
Nickerson HJ 17:51
Niederman M
Pneumonia: The ongoing challenge, **7**:77
Cardiopulmonary Problems in the Office
Cardiac patients with pneumonia, **7**:33
Norman DC 3:49

OPQ

Oderda GM 1:85
Olsen J 10:31
Olsen KD 8:45
Olshaker JS 14:156
Orton D 10:31
Osborne LF 20:57
Oster SB 14:122
Ourada C 10:31
Overturf GD 20:47
Panaro V 2:54
Papa CM 16:104
Partain CL 11:164
Patel H 16:86
Patnaude E 6:96
Patterson WP 8:84
Patton D 6:47
Patzakis MJ 21:81
Pearlman K 20:57
Pelletier E 11:74
Pelletier GB 11:74
Pelz D 2:109
Pepe PE 20:86
Perry MC 8:84
Petersen LR 14:102
Philbrick JT 6:59
Phillips RS
Gonorrheal testing, **13**:64
Unsuspected chlamydia, **16**:93
Piano G 5:100
Piantadosi CA 12:46
Pickleman J 11:135
Pinkerton RE 10:49
Pitsakis P 16:59
Pizzo P 15:18
Plehn JF 12:61
Poller L 11:173
Post PJ 18:41
Poupard J 16:59
Pressman HL 1:82
Preston RA 6:100
Proffitt RD 13:147
Propp DA 19:41
Pruett RC 17:20
Pullano WE 11:84
Quinn TC 3:173
Quyyumi AA 20:104

RS

Ramsey WH 11:84
Ramzy A 5:100
Raskin A 6:96
Rauch SD 18:16
Ravich W 1:51
Ray VG 17:39
Raymond JR 2:117
Raymond PA 2:117
Redfield RR 3:176
Redus M 14:102
Reed WG 8:92
Reveille RM 6:37
Richardson H 2:45
Rickets RR 10:31
Riedel CS 19:89
Ringenberg QS 8:81
Rinzler D 11:74
Roberts JR
When a child dies suddenly, **6**:74
Emergency Tips from the Literature: **1**:11; **2**:13; **3**:11; **4**:11; **6**:11; **7**:13; **8**:11; **9**:9; **10**:9; **11**:11; **12**:11; **13**:9; **14**:9; **15**:11; **16**:12; **18**:9; **19**:15; **20**:9; **21**:8
Roberts MS 14:49
Roberts RJ 3:151
Robinson WA 19:89
Rodnick JE 8:109
Rogers MF 3:178
Roland D 6:53
Rose SR 18:9
Rosen P 21:168
Rosenbaum GS 14:166
Rosenthal JL 11:84
Rotche R 15:59
Roth D 6:100
Rothmund M 15:45
Royal HD 1:89
Rubin JL 5:53
Rückert K 15:45
Rupert EG 14:195
Saffle JR 12:66
Safran C 13:66
Safrany L 11:84
Safrin S 10:83
Sahn SA 1:33
Sainsbury SJ 16:86
Salata RA 17:114
Salen G 11:131
Salomone JA III 19:89
Saltzman BR 3:178
Samuels MA 19:21
Sattler SL 19:11 (letter)
Tricks of the trade: **18**:41
Sawyer LA 14:102
Sayre MR 17:36
Schaffer C 1:82
Schellhas KP 19:73
Schiff MJ 7:47
Schmitz BF 1:85

Schoene RB 5:21
Schossow GW 2:103
Schultz D 7:33
Schuman BM 16:67
Schwartz JG 1:40
Schwartz NS 21:63
Schwartz S 17:55
Schwentker FN 5:123
Scott S 18:41
Seigler M 6:53
Shanies HM 9:71
Sharbrough F 18:58
Shaw EW 20:92
Shayegani M 1:82
Shenasa M 9:42
Sheretz EF 14:68
Shiels MT 10:33
Shlaes DM 17:114
Siegel D 10:83
Siegel JH 11:84
Siera MR 8:68
Silverstein MD 6:53
Singer C 20:47
Singer J 6:74
Sivertson KT 3:173
Sklar D 12:51
Slovis CM
Diabetic ketoacidosis diagnosis, **8**:20
Two-minute test for meningitis, **21**:41
Smith DL
It's bursitis, but what type? **8**:71
Digital ischemia, **17**:119
Smith ES 21:111
Smith MB
Trauma Rounds
Biliary tract injuries, **5**:95
Traumatic pseudoaneurysm, **13**:147
Smith RP 1:82
Sobotka PA 15:59
Solomon J 6:76
Solow BK 2:103
Sonnenberg L 12:42
Sonzogni JJ Jr.
Assessing the injured ankle, **1**:62
Assessing the injured knee, **3**:127
Sood R 21:171
Soutter I 5:100
Spencer CA 17:75
Spierings ELH 14:164
Squires K 15:26
Starich GH 13:61
Stark E 11:104
Stasiak J 11:74
Staszewski H 15:69
Steele MT 19:89
Steere AC 10:49
Steinberg H 19:63
Stenzel M 11:84
Sternbach GL 8:131
Stewart SM 8:45
Stocking CB 6:53
Strickland D 5:41
Stuckey JH 1:40
Sudarsky L 8:51
Sullivan JL 1:89
Sullivan M 2:45
Sullivan RJ 1:73
Sussman SJ
Diagnosis at a Glance: **1**:57; **2**:41; **3**:75; **4**:71; **5**:59; **6**:103; **7**:73; **8**:105; **9**:36; **10**:97; **11**:167; **12**:57; **13**:111; **14**:107; **15**:49; **16**:73; **17**:89; **18**:67; **19**:35; **20**:107
Syfert DF 13:78
Syrogianopoulos GA 8:45

T

Talan D 20:47
Tarver RD
Misplaced Tube: **2**:119; **6**:131; **8**:175; **10**:113; **12**:101; **16**:137; **18**:97; **20**:131
Taswell HF 10:33
Taylor WC 13:66
Tchou PJ 9:42
Tedeschi AA 11:164
Tepas JJ III 12:45
Tharrat SR 14:154
Théroux P 11:74
Thill KA 19:11 (letter)
Thistle JL 11:138
Thomas RJ 14:102
Thomson S 20:82
Timberlake GA
Trauma Rounds
Isolated blunt splenic trauma, **1**:73
Ureteral injury, **3**:147
Biliary tract injuries, **5**:95
Pleural effusion after blunt penetrating trauma, **11**:93
Traumatic pseudoaneurysm, **13**:147
Brown recluse spider envenomation, **14**:39
Lipstick sign, **17**:46
Iatrogenic pseudoaneurysm of the radial artery, **21**:69
Tint GS 11:135
Tipple M
Influenza—the deadly effects, **17**:61
Now is the time to vaccinate, **17**:84
Titus AF 8:68
Tomlanovich MC 2:45
Torres CA 21:37
Trust A 19:63
Turino GM 20:70
Turner L 21:168
Twanmoh VH
Legal Rounds
Restraint in the ED, **8**:162
Switching counsel in midstream, **10**:55

UVW

Valentine MW
Trauma Rounds
Biliary tract injuries, **5**:95
Traumatic pseudoaneurysm, **13**:147
Valley P 2:45
van Gijn J 13:105
Van Hoesen KB 12:46
van Leeuwenhoek A 12:77
Van Steigman G 6:37
Varian DW 4:82
Verchoor J 21:111
Verghese A 20:68
Verweij RD 13:105
Wagner DK 8:7
Walker ME 14:195
Wallerstein RO 8:145
Ward JD 10:37
Ward JI 3:49
Ward KR 1:73
Ward RS 12:66
Warden GD 12:66
Wasserman M 18:91
Watanabe A 21:111
Waters DD 11:74

continued

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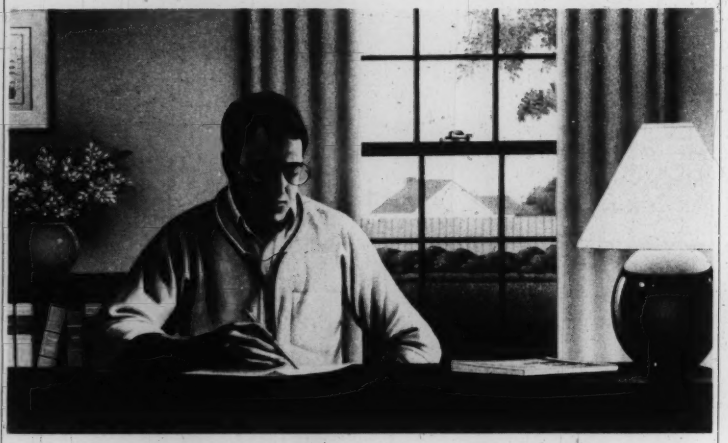

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AUTHOR INDEX

Weber D 19:41
Wehrmacher WH 15:59
Weiler BR 17:55
Weiner BH 16:123
Weintraub NT 16:24
Weisberg LS 12:87
Weiss R 6:74
Weist PM 17:114
Welch KMA 14:114
Wendeler M 16:59
Wernick R 17:119
Wertheimer A 16:93
Wheby MS 14:179
White W 12:51
Whitten CE
Intubation for the Primary Care Physician
Endotracheal anatomy, **8**:171
Preintubation evaluation, **10**:107
Equipment for airway management, **12**:91
Oral intubation in adults, **14**:81
Common intubation errors, **15**:91
Tests for tube placement, **17**:93
Intubating the child, **19**:81
Widmer K
Tricks of the Trade: **6**:96; **21**:111
Wijdicks EFM 13:105
Wilkes CH 19:73
Wilkins J 21:81
Winick M 4:28
Wolfe RE 21:170
Wood JR 10:33
Wright HL 19:11

XYZ

Yarbro JW 8:84
Yawn BP 14:195
Yearly L 20:116
Yoshikawa TT 18:91
Yu VL 5:53
Zaiser DK 5:63
Zelenik RD 1:73
Zinsmeister AR 2:53
Zipperer WP 4:82
Ziring BS 11:141
Zun L 18:71